DOCUMENT RESUME

ED 162 734 PS 010 214

TITLE	Obstetrical Practices in the United States, 1978. Hearing Before the Subcommittee on Health and Scientific Research of the Committee on Human Resources, United States Senate, Ninety-Fifth Congress, Second Session.
INSTITUTION	Congress of the U.S., Washington, D.C. Senate Committee on Human Resources.
PUB DATE	17 Apr 78
NOTE	187p.; Not available in hard copy due to small print size on many pages; Pages 87-129 of the original document are copyrighted and therefore not available and not included in the pagination
EDRS PRICE	MF-$0.83 Plus Postage. HC Not Available from EDRS.
DESCRIPTORS	*Birth; Changing Attitudes; *Hearings; *Medical Care Evaluation; *Perinatal Influences; *Pregnancy; *Prenatal Influences
IDENTIFIERS	*Congress 95th

ABSTRACT

This document presents the proceedings of a U.S. Senate subcommittee hearing on obstetrical practices in the United States. Specific issues examined include the use of fetal monitors, the increasing rate of cesarean sections, elective induction of labor, and the use of drugs in pregnancy and labor. Information is presented in the form of statements and testimony by expert witnesses, articles and publications, pertinent communications to and from subcommittee members and experts, and tables and charts. (JMB)

****
* Reproductions supplied by EDRS are the best that can be made *
* from the original document. *
****

U.S. DEPARTMENT OF HEALTH,
EDUCATION & WELFARE
NATIONAL INSTITUTE OF
EDUCATION

THIS DOCUMENT HAS BEEN REPRODUCED EXACTLY AS RECEIVED FROM THE PERSON OR ORGANIZATION ORIGINATING IT. POINTS OF VIEW OR OPINIONS STATED DO NOT NECESSARILY REPRESENT OFFICIAL NATIONAL INSTITUTE OF EDUCATION POSITION OR POLICY

PS

ED162734

OBSTETRICAL PRACTICES IN THE UNITED STATES, 1978

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

OF THE

COMMITTEE ON HUMAN RESOURCES
UNITED STATES SENATE

NINETY-FIFTH CONGRESS

SECOND SESSION

ON

EXAMINATION OF OBSTETRICAL PRACTICES SUCH AS THE USE OF FETAL MONITORS, THE INCREASING RATE OF CESAREAN SECTIONS, ELECTIVE INDUCTION OF LABOR AND THE USE OF DRUGS IN PREGNANCY AND LABOR

APRIL 17, 1978

Printed for the use of the Committee on Human Resources

PS010214

U.S. GOVERNMENT PRINTING OFFICE
30-961 WASHINGTON : 1978

COMMITTEE ON HUMAN RESOURCES

HARRISON A. WILLIAMS, Jr., New Jersey, *Chairman*

JENNINGS RANDOLPH, West Virginia
CLAIBORNE PELL, Rhode Island
EDWARD M. KENNEDY, Massachusetts
GAYLORD NELSON, Wisconsin
THOMAS F. EAGLETON, Missouri
ALAN CRANSTON, California
WILLIAM D. HATHAWAY, Maine
DONALD W. RIEGLE, Jr., Michigan

JACOB K. JAVITS, New York
RICHARD S. SCHWEIKER, Pennsylvania
ROBERT T. STAFFORD, Vermont
ORRIN G. HATCH, Utah
JOHN H. CHAFEE, Rhode Island
S. I. HAYAKAWA, California

Stephen J. Paradise, *General Counsel and Staff Director*
Marjorie M. Whittaker, *Chief Clerk*
Don A. Zimmerman, *Minority Counsel*
Gregory Fusco, *Minority Staff Director*

Subcommittee on Health and Scientific Research

EDWARD M. KENNEDY, Massachusetts, *Chairman*

CLAIBORNE PELL, Rhode Island
GAYLORD NELSON, Wisconsin
WILLIAM D. HATHAWAY, Maine
HARRISON A. WILLIAMS, Jr., New Jersey (ex officio)

RICHARD S. SCHWEIKER, Pennsylvania
JACOB K. JAVITS, New York
JOHN H. CHAFEE, Rhode Island

Lawrence Horowitz, M.D., *Professional Staff Member*
David Winston, *Minority Counsel*

CONTENTS

CHRONOLOGICAL LIST OF WITNESSES

APRIL 17, 1978

Page

Kennedy, Dr. Donald, Commissioner, Food and Drug Administration, Public Health Service, Department of Health, Education, and Welfare, accompanied by Dr. Marion Finkel, Associate Director for New Drug Evaluation, Bureau of Drugs; and Richard Cooper, Chief Counsel...... 9

Caldeyro-Barcia, Roberto, M.D., president, International Federation of Gynecologists and Obstetricians; director, the World Health Organization's Latin American Center for Perinatology and Human Development, Montevideo, Uruguay, accompanied by Doris Haire, president, American Foundation for Maternal and Child Health, Inc., New York, N.Y.; Arnold D. Haverkamp, M.D., Denver General Hospital, Denver, Colo.; and Ronald R. Rindfuss, Ph. D., department of sociology, University of North Carolina, a panel...... 50

Nichols, Ervin D., M.D., director, practices activities, the American College of Obstetricians and Gynecologists, accompanied by Richard Paul, M.D., department of obstetrics and gynecology, University of Southern California at Los Angeles; George Ryan, M.D., department of obstetrics and gynecology, Memphis, Tenn.; and Leonard Smith, M.D., private practitioner, Hyannisport, Mass., a panel...... 184

STATEMENTS

American College of Obstetricians and Gynecologists, Ervin D. Nichols, M.D., director, prepared statement...... 200

Caldeyro-Barcia, Roberto, M.D., president, International Federation of Gynecologists and Obstetricians; director, the World Health Organization's Latin American Center for Perinatology and Human Development, Montevideo, Uruguay, accompanied by Doris Haire, president, American Foundation for Maternal and Child Health, Inc., New York, N.Y.; Arnold D. Haverkamp, M.D., Denver General Hospital, Denver, Colo.; and Ronald R. Rindfuss, Ph. D., department of sociology, University of North Carolina, a panel...... 50

Children's Hospital Research Foundation, Cincinnati, Ohio, Richard E. Butcher, associate professor of research pediatrics and psychology, Institute for Developmental Research, prepared statement...... 149

Denver General Hospital, Arnold D. Haverkamp, M.D., department of sociology, prepared statement...... 57

Haire, Doris, B., D.M.S., chairwoman, National Women's Health Network, prepared statement...... 142

Kennedy, Dr. Donald, Commissioner, Food and Drug Administration, Public Health Service, Department of Health, Education, and Welfare, accompanied by Dr. Marion Finkel, Associate Director for New Drug Evaluation, Bureau of Drugs; and Richard Cooper, Chief Counsel...... 9

- Prepared statement...... 35

Nichols, Ervin D., M.D., director, practices activities, the American College of Obstetricians and Gynecologists, accompanied by Richard Paul, M.D., department of obstetrics and gynecology, University of Southern California at Los Angeles; George Ryan, M.D. department of obstetrices and gynecology, Memphis, Tenn.; and Leonard Smith, M.D., private practitioner, Hyannisport, Mass., a panel...... 184

- Prepared statement...... 200

Page

Paul, Richard, M.D., department of obstetrics and gynecology, University of Southern California at Los Angeles, prepared statement 203

Ryan, George, M.D., professor of obstetrics and gynecology, professor of community medicine, University of Tennessee Center for the Health Sciences, prepared statement 206

Smith, Leonard, M.D., chairman, department of obstetrics and gynecology, Cape Cod Hospital, prepared statement 213

University of Florida Medical School, Yvonne Brackbill, graduate research professor, departments of psychology and obstetrics and gynecology, prepared statement 130

University of North Carolina, Chapel Hill, N.C., Ronald R. Rindfuss, department of sociology, prepared statement 67

ADDITIONAL INFORMATION

Articles, publications, etc.:

Cultural Warping of Childbirth: A Case of Misguided Kindness 123

Cultural Warping of Childbirth, by Doris B. Haire, D.M.S., copresident, International Childbirth Education Association 87

Extent and Character of Drug Consumption During Pregnancy, by Paul L. Doering, M.S., Ronald B. Stewart, M.S., from JAMA, February 27, 1978, vol. 239. No. 9 11

Fetal Monitoring, by Roberto Caldeyro-Barcia, M.D., F.A.C.O.G. (Hon.), director, Latin American Center of Perinatology and Human Development, Pan American Health Organization 172

Lasting Behavioral Effects of Obstetric Medication on Children: Research Findings and Public Policy Implications, by Yvonne Brackbill 130

Elective Induction of Labor: Advantages and Disadvantages, by Roberto Caldeyro-Barcia, M.D., F.A.C.G. (Hon.), F.A.C.S. (Hon.), director, Latin American Center of Perinatology and Human Development, Pan American Health Organization (PAHO) 161

Pregnant Patient's Bill of Rights and the Pregnant Patient's Responsibilities 126

Communication to:

Horowitz, Dr. Larry, professional staff member, Subcommittee on Health and Scientific Research, from J. Edward Sweet, Jr., administrator, the Alexandria Hosptial, Alexandria, Va., April 26, 1978 (with enclosure) 218

Javits, Hon. Jacob K., a U.S. Senator from the State of New York, from Hon. Donald Kennedy, Commissioner, Food and Drug Administration, Aug. 14, 1978 224

Kennedy, Hon. Donald, Commissioner, Food and Drug Administration, from Senator Jacob K. Javits, May 16, 1978 222

Kennedy, Hon. Edward M., a U.S. Senator from the State of Massachusetts, from Yvonne Brackbill, graduate research professor, University of Florida, Gainesville, Fla., April 18, 1978 141

Schweiker, Hon. Richard S., a U.S. Senator from the State of Pennsylvania, from Yvonne Brackbill, graduate research professor, University of Florida, Gainesville, Fla., April 18, 1978 152

Tables, charts, etc.:

Extent of Fetal Monitoring in Hospitals in the United States, by the Senate Subcommittee on Health and Scientific Research, 1977 4

OBSTETRICAL PRACTICES IN THE UNITED STATES, 1978

MONDAY, APRIL 17, 1978

U.S. SENATE,
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH
OF THE COMMITTEE ON HUMAN RESOURCES,
Washington, D.C.

The subcommittee met, pursuant to notice, at 9:45 a.m., in room 457, Russell Senate Office Building, Senator Edward M. Kennedy (chairman of the subcommittee) presiding.

Present: Senators Kennedy, Javits and Schweiker.

OPENING STATEMENT OF SENATOR KENNEDY

Senator KENNEDY. We will come to order.

Childbirth—the very word evokes a sense of joy and wonder; the true miracle of life renewing itself. No parent will ever forget the mixture of hope and fear that accompanies the onset of labor: hope that the baby will be well; fear that it will not. And no parent will ever forget the exhilaration of a normal birth.

Pregnancy and childbirth are very vulnerable times in parents' lives. They are unusually dependent on their physician to guide them through the strange mixture of emotional and physical changes. And it is a very vulnerable time for the fetus as well, for what the mother does or does not do—the medicines she takes, the cigarettes she smokes, the alcohol she drinks—may have a profound effect on its health and development. And we will learn today that what the obstetrician does or does not do—whether ultrasound is used, X-rays are taken, fetal monitoring is employed, inhalation anesthesia is used, or labor is induced—may have an equally profound effect on the health of the newborn infant.

Modern obstetrics has significantly reduced the risk of childbirth to both the mother and child. All Americans can be proud of the fact that the maternal mortality rate today is one-fortieth of what it was in 1930; that infant mortality is one-fourth of what it was then; that perinatal mortality is 25 percent lower today than just 10 years ago.

Yet problems remain. The United States has only the 12th lowest infant mortality rate in the world. And the American lifestyle, combined with the modern practice of obstetrics, has created serious additional health questions and problems for the mother and baby.

The overuse and misuse of prescription and over-the-counter drugs in our society generally seems to continue in pregnancy as well, with particularly dangerous implications. A recent study at the University of Florida College of Pharmacy indicated that 93 percent of the 168 pregnant women studied used 5 or more drugs; 93 percent of these took aspirin, 56 percent antacids, 37 percent antibiotics, 41 percent general cough and cold preparations, 18 percent barbiturates, and 18 percent antihistamines.

An epidemiologic study of drug use in Texas during pregnancy revealed a range of from 3 to 29 agents used, with an overall mean of 10 per patient.

All of this takes place in spite of the knowledge of the vulnerability of the fetus to foreign substances and the absence of knowledge about the short and long term effects of most of these medications. The mother who takes several drugs during pregnancy, and the physician who prescribes them, are generally entering unchartered waters where the degree of risk is almost completely unknown, and the possibility of tragedy always lurks in the background.

Today, we will hear what we do and do not know about the effects of drugs on the fetus; why we do not know more; and how we can develop the needed information. But the message to expectant mothers is loud and clear—take as few drugs as you can, take them only when medically necessary, and ask your doctor whether the short- and long-term effects of the medication on the fetus are known.

We will also hear today about serious questions raised about several common obstetrical practices made possibly by technological advances. As in many areas of medicine, the development of obstetrical technology far outstrips our capacity to assess its appropriate value. As a result, common practice is established before appropriate practice can be defined. A perfect example of this is the widespread use of ultrasound equipment during pregnancy and labor. One of its uses is in fetal monitoring during labor. The American College of Obstetrics and Gynecology believe it to be safe, and recommend it for all obstetric patients. New York City wishes to require such monitoring of all obstetrical patients in city hospitals.

Yet, since 1970, scientists in the Food and Drug Administration have been concerned about how little is known about its safety or its long-term public health effects. Eight years ago they warned:

> The current state of knowledge concerning the biological hazard of ultrasound, in the light of the projected expansion in the use of ultrasound, is a matter of great concern—it is essential that the biologic hazards of ultrasound be evaluated and that the relative hazard of ultrasound and X-rays be defined.

They were right about the expansion of use since 1970—it has occurred. They were right about the need for data—but little has been done to generate it.

As a result, the procedure is widely used, millions of children are exposed, but the safety, particularly the long-term safety, of the procedure is unknown. It may turn out to pose no risk at all. But the time to find out is before millions of children are exposed. Otherwise, we are playing an unjustifiable game of Russian roulette with the health of our children.

I have proposed legislation, S. 2466, to create the National Institutes of Health Care Research, designed to address this very problem. Research would be supported, which, in this field, would attempt to answer the following questions:

When is fetal monitoring appropriate? Does it alter outcomes in all kinds of pregnancies—if not, in which cases is it most effective. What is the correlation between monitoring and cesarean rates? What is the long-term effect of fetal monitoring devices using ultrasound on the health of children?

This legislation is designed to provide answers that will enable us to get the best technology has to offer, and yet avoid the problems that inevitably come from overuse and misuse. It has already been favorably reported by this subcommittee, and I expect it to pass the Senate by June.

In this morning's hearings we will also explore the problems associated with elective induction, a procedure to begin labor for the convenience of either the patient or physician. Are there justifiable reasons for this procedure, or do the attendant risks outweigh the benefits? We will seek to get answers this morning.

Finally, I want to thank my friend and colleague, Senator Javits, for asking that this hearing be developed. By assuring that these disturbing questions get raised in a public forum, he is increasing the likelihood that sufficient resources will be committed to developing answers—answers that will improve the health and well being of expectant mothers and their children for years to come.

I am attaching to this statement a summary of an informal staff survey of hospitals around the country designed to show the extent of fetal monitoring used and the number of cesarean sections performed at those institutions. We will hear more about this subject from our witnesses.

[The information referred to follows:]

The following survey was conducted by the staff of the Senate Health and Scientific Research Subcommittee during the past month. Many of the hospitals gave approximate responses.

HOSPITAL	NUMBER OF BIRTHS, 1976	PERCENT OF PATIENTS MONITORED, 1977	PERCENT OF CAESARIAN SECTIONS, 1977
Brookwood Hosp. Birmingham, Ala.	1344	all	15%-20%
Maricopa County General Phoenix, Ariz	4092	almost all	12.5%-13%
Johns Hopkins Baltimore, Md.	2143	100%	16%
Univ. Southern California, Los Angeles	12,392	48%	12%
Stanford Stanford, CA.	2352	85%-90%	13%
Cedars Sinai Medical Center Los Angeles, CA.	3589	routine	17%
Presbyterian Aurora Medical Center Denver, Colo.	570	50%-60%	12%
Hartford Hosp. Hartford, Conn.	2809	88%-89%	20%
Yale New Haven New Haven, Conn.	4259	65%-75%	16%
Columbia Hospital for Women Wash., D.C.	3857	99%	25%
George Washington Wash., D.C.	2600	all	20%
Georgetown Univ. Wash., D.C.	1672	almost 100%	7/76-6/77=20.9% 7/77-12/77=22.4%
Greater S.E. Memorial Wash., D.C.	1938	100%	21.3%
Providence Hosp. Wash. D.C.	1167	30%	10%-12%
James M. Jackson Memorial Hosp. Miami, Fla.	5818	50%	17.9%
Univ. of Chicago Hosp. & Clinics Chicago, Ill	3344	50-100%	11%
Indiana Univ. Indianapolis, Ind.	1163	80%	10.5%

HOSPITAL	NUMBER OF BIRTHS, 1976	PERCENT OF PATIENTS MONITORED, 1977	PERCENT OF CAESARIAN SECTIONS, 1977
St. Francis Hosp. Wichita, Kan	1081	75%	10%
Hopkins County Madisonville, Ky.	1034	80%	12%
Wichita General Wichita, Kan	1594	50%	25%
Sibley Hosp. Washington, D.C.	1684	64.7%	21%
Nortons Childrens Louisville, Ky.	1583	all	15%
Rapides General Alexandria, La.	808	80%	15%
Mid Maine Medical Center Waterville, Maine	886	10%	less than 10%
Beth Israel Boston, Ma.	2079	80%	15%
St. Margarets Hosp. Dorchester, Mass.	2911	75%-80%	20%
St. Joseph's Mercy Pontiac, Mich.	2168	less than 20%	13.3%
Univ. of Minn. Minneapolis, Minn.	662	80%-85%	13%
Hinds General Hosp. Jackson, Miss.	1022	less than 50%	20%
Univ. Hosp. Jackson, Miss.	3506	80%	14%
Barnes Hosp. St. Louis, Mo.	3439	60%-70%	17% private 14% clinic
St. Vincent's Billings, Mont.	1902	50%	15.5%
Sunrise Hosp. Las Vegas, Nev.	1190	100%	12.7%
Elliot Hosp. Manchester, N.H.	903	all for 30 minutes	10%
Riverview Hosp. Redbank, N.J.	1527	routine	13%
Newark Beth Israel Newark, N.J.	1351	all	20%
Bernalille County Medical Center Albuquerque, N.M.	2327	75%	10%
Mt. Sinai New York, N.Y.	3050	most	25%

HOSPITAL	NUMBER OF BIRTHS, 1976	PERCENT OF PATIENTS MONITORED, 1977	PERCENT OF CAESARIAN SECTIONS, 1977
Columbia Presbyterian New York, N.Y.	2507	100%	20%
N.C. Memorial Chapel Hill, N.C.	1195	all high risk patients	12%-15%
Cleveland Metropolitan Memorial Cleveland, Oh.	2602	55%	13%
St. Anthony's Hosp. Oklahoma City, Okla.	1289	50%-60%	15%
Univ. of Penna. Hospital Philadelphia, Pa.	1149	62%-65%	12%-15%
Mercy Hospital Scranton, Pa.	1125	all	10%
Woman's & Infants Services Providence, R.I.	4932	100%	17%
Medical Univ. Hosp. Charlestown, S.C.	2729	70%-72%	12.5%
Richland Memorial Columbia, S.C.	2079	33%	16.7%
St. Luke's Hosp. Aberdeen, S.D.	539	100%	11.4%
City of Memphis Hosp. Memphis, Tenn.	5836	80%	11.6%
Vanderbilt Univ. Nashville, Tenn.	1390	90%	12%
Herman Hosp. Houston, Texas	1477	80%	20%
St. Marks Hosp. Salt Lake City, Utah	1453	100%	10%-15%
Medical Center Hosp. of Vermont Burlington, Vt.	1812	30%	17%
Arlington Hosp. Arlington, Va.	1050	90%	18%
Alexandria Hosp. Alexandria, Va.	2592	almost all	23.5% [illegible]
Univ. of Va. Hosp. Charlottesville, Va.	1100	60%	20%
Madison General Madison, Wis.	1949	50%	17%-18%
Univ. Hosp. Ann Arbor, Mich.	1282	75%	21%
Mercy Medical Cen. Dubuque, Iowa	878	80%	7.5 %

HOSPITAL	NUMBER OF BIRTHS, 1976	PERCENT OF PATIENTS MONITORED, 1977	PERCENT OF CAESARIAN SECTIONS, 1977
Haris County (Jefferson Davis) Houston, Texas	9742	75%	20%-25%
Abbott Northwestern Minneapolis, Minn.	1106	60%-70%	17%
University Hosp. Seattle, Wash.	1682	90%	14.9%
Memorial Hosp. of Natrona County Casper, Wy.	1153	70%	10%-11%

The following data was supplied to the subcommittee by Helen Marieskind, Di.P.H., Consultant, Office of the Secretary, H.E.W. and Executive Director of Endstage Renal Disease Network #2.

Year	# of C-Sections	# deliverits	% of C Sections
1968	172,000	3,435,000	5.0
1971	194,000	3,459,000	5.6
1972	227,000	3,352,000	6.7
1973	246,000	3,238,000	7.5
1974	286,000	3,239,000	8.7
1975	328,000	3,328,000	9.9
1976	378,000	3,329,000	11.4

There were 194,000 Caesarian Sections in the United States in 1971. There were 378,000 Caesarian Sections in the United States in 1976. That is a 94.84% increase in that period. The number of births decreased during this same period by -3.75%.

Senator Kennedy. Senator Schweiker.

Senator Schweiker. Today the subcommittee will hear a discussion of modern obstetrical practices. I view this hearing as part of the subcommittee's continuing effort to inform the American people of both the progress and problems of modern medical practice in this country.

The subcommittee will focus on four important issues: (1) the use of drugs during pregnancy, (2) the increasing incidence of elective inductions of labor, (3) the increased incidence of cesarean sections, and (4) the use of new technology in the form of fetal heart monitors. These issues are very complicated and all fundamentally raise the issue of how to best inform both the physician and the patient so that together they may make a reasonable assessment of both the benefits and the risks of various drugs and procedures.

If inadequacies in this information process exist, how can they be remedied? Are Government agencies, such as FDA, adequately doing their job both to inform the physician and educate the public? Is the medical profession requiring a high enough standard of care to guard against harmful practices? These are the major issues I hope to see addressed.

As the father of five who has been through labor and delivery with my wife, I know, firsthand, the mixture of both anxiety and joy that attends childbirth. I also know that the people of this country are entitled to the best obstetric care attainable. I believe that this hearing may help us achieve that goal. I too want to commend Senator Javits for his interest in this matter.

Thank you, Mr. Chairman.

Senator Kennedy. Senator Javits.

Senator Javits. I would like to express my appreciation to Senator Kennedy, chairman of the Human Resources Health Subcommittee, and Senator Schweiker, the ranking minority member of the subcommittee, for agreeing to convene this hearing, which I recently requested.

The purpose of the hearing is to expose and examine a controversy, the outcome of which affects the health and well-being of every American, and has far-reaching implications for the role of medicine in our society. The issue here is whether the natural process of childbirth should be disrupted unnecessarily.

Fortunately, the incidence of complicated pregnancies is low—in fact, more than 90 percent of all births are normal and uncomplicated. Yet, our society has come to treat pregnancy as an illness and pregnant women as patients.

Routinely drugs are administered, surgical procedures are performed, and an array of instruments and devices are employed, many of which it appears have never been conclusively tested for their relative risk and benefit.

In today's world of ever advancing medical technology—which, by and large, has meant for many people the difference between life and death, pain and comfort—we have come to view childbearing either as a sickness in need of treatment, or as a function to be manipulated to fit schedules convenient to physicians, hospitals, and parents.

Unfortunately, I fear we may have neglected thoroughly and accurately to assess the accompanying risks and benefits.

As a long-time advocate of generous Federal support for biomedical research, I have watched with unending admiration the growth and development of our scientific knowledge; I applaud the great strides we have made in the field of curative medicine. But I am concerned that in our zeal for conquering illness and disease we may have, in the particular case of childbirth, overstepped the boundaries which separate medically justified from convenient or overzealous medical interventions.

We may be taking unnecessary risks with the lives and well-being of our mothers and children, since, as I have already noted, the overwhelming majority of births are without medical complications.

The issues we will be addressing today are important for this reason; there is much evidence which suggests that the physical and emotional well-being of an individual is shaped, in part, by the progression of pregnancy, labor, and delivery. As such, it is critically important that any woman who contemplates childbirth be aware of the potential risks associated with those medical practices which intervene in the course of a normally progressing pregnancy and labor.

This is not to say that prenatal care is not of tremendous benefit for the health of the mother and child. To the contrary, I am convinced that much of the improvement we have experienced in infant mortality is attributable to the increasing availability and accessibility of high-quality prenatal care services. Nor is it to say that there is not an appropriate role for medicine in treating women whose pregnancies show signs of medical complications. For those cases, our technology offers much hope for assuring the continued health and safety of both the mother and baby.

But in the past several months, I have been impressed by the persuasive arguments of a number of very dedicated, highly knowledgeable individuals who are calling for extensive reform in our approach to the management of normally progressing births.

Today we will focus on four specific obstetrical practices—the use of drugs in pregnancy and labor, elective induction of labor, the rising incidence of cesarean sections, and the safety and efficacy of certain technological innovations and medical devices such as fetal heart monitors—in an effort to determine what we do and do not know about the short- and long-term effects of these practices on the mother and child.

I look forward to receiving testimony from our witnesses on each of these subjects.

Senator KENNEDY. Thank you very much.

We will start with the Commissioner of Food and Drugs, Food and Drug Administration.

STATEMENT OF DONALD KENNEDY, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ACCOMPANIED BY DR. MARION FINKEL, ASSOCIATE DIRECTOR FOR NEW DRUG EVALUATION, BUREAU OF DRUGS; AND RICHARD COOPER, CHIEF COUNSEL

Dr. KENNEDY. Mr. Chairman, with me are Richard Cooper, Chief Counsel of FDA, and Dr. Marion Finkel, Associate Director of the Bureau of Drugs for New Drug Evaluation.

The use of drugs and medical devices in obstetrical practice is a subject of very special concern to the Food and Drug Administration. The risks associated with their use in pregnant women involve not one but two lives: One just beginning, the other exposed to unusual physiological stress. Misuse or overuse of drugs or devices under these conditions can cause short term hark; and—as we learned, to our sorrow, in the case of diethylstilbestrol (DES)—they can also produce adverse effects in the offspring that become patent long after the exposure.

Senator **Kennedy**. At the outset, let me point out that this is an extremely complex and difficult area to make judgments in terms of all these procedures, because of the very important ethical questions in terms of testing that we require in other areas. The sensitivity that we have in terms of testing, in terms of expectant mothers, and the rest, as I understand it, I will be interested in whether you agree—is one of the most difficult ones to study because of the ethical questions that result about the use of drugs and the devices.

Dr. **Kennedy**. Yes; that is absolutely true. It is complicated, I think, for two reasons: there are two kinds of risks to worry about; and two kinds of benefits. So that sort of equation is much more complicated.

The other problem is that we do not want our concern for the rights of subjects to result in the wholesale withdrawal of some important rights for patients.

As many people have pointed out, pregnant women are a therapeutically deprived class in some sense in this country because of the ethical constraints associated with testing. I do not think there are very easy solutions to this problem, but it is just a very troublesome one.

I thought I would begin this discussion, Mr. Chairman, with a brief survey of the important changes taking place in obstetrical care, and of the role my agency plays in assuring safe and effective use of obstetrical drugs and devices.

Then I want to explore a few other issues that deserve special emphasis, or are of special interest to the subcommittee.

I would just make a few points about what has happened to management of pregnancy, and the care of obstetrical patients over the past two decades.

Disorders of pregnancy have become better understood as a result of the scientific research efforts.

The use of drugs during pregnancy has steadily declined, that is for drugs not related to pregnancy. The number of warning restrictions, and what we think is the general increase in consciousness of physicians and patients about the risks associated with such use are contributing to that.

Senator **Kennedy**. I think that is important to understand the dimension of the problem. You say the use of drugs during pregnancy is steadily declining.

We have the Florida study, and one other study that would indicate there is still very wide use of drugs during this period. I would just be interested in whether you have really a statistical base for a reduction in the use of drugs, and, second, I would be interested in the comment of yours about the continued use, that is whether we are getting the appropriate use during this period.

[A copy of the Florida study follows:]

The Extent and Character of Drug Consumption During Pregnancy

Paul L. Doering, MS, Ronald B. Stewart, MS

• One hundred sixty-eight obstetrical patients' conditions were monitored prospectively throughout the prenatal, perinatal, and postpartum periods to obtain data on maternal drug consumption. In the prenatal period, all patients received at least two different drug products: 93.4% received five or more, while one patient reported taking 32 different products. The average number of drug products used in the prenatal period was 11.0. The mean perinatal exposure in patients undergoing vaginal delivery was 7.0. Analysis by therapeutic category was performed. Information gathered confirms the fact that pregnant women do take a large number of different types of medications, the consequences of which remain unknown.

(*JAMA* 239:843-846, 1978)

CONSIDERABLE attention to the problem of drug-induced congenital malformation resulted following the thalidomide tragedy of the early 1960s.[1,2] Likewise, the effects on the female offspring of maternal administration of diethylstilbestrol further underlined the need to evaluate drugs consumed during pregnancy.[3,4] Drug selection for intercurrent diseases during pregnancy is often influenced by known or suspected harmful effects of such drugs on the fetus. In today's society, self-medication is a medical and social institution. Many of the complaints during early pregnancy are those for which well-advertised nonprescription drugs claim dramatic relief. Unfortunately, the absolute safety of such products in pregnancy has not yet been assessed. Additionally, consumption of medications before the diagnosis of pregnancy poses a particular hazard because the first trimester is most sensitive to drug effects on the fetus.

These and other problem areas point out the necessity for closely monitoring the effects of drugs and chemicals on the pregnant woman and her offspring. Historically, most investigations were conducted in retrospect, relying on sketchy, often incomplete information about pregnancies that yielded malformed infants. Retrospective studies begin with the birth of a malformed infant and attempt to identify causative factors responsible for the anomaly. The tendency for a mother to attribute the birth of a deformed child to some unusual event during her pregnancy greatly complicates objective investigation. For this and other reasons, retrospective studies have generally proved unsatisfactory, frequently resulting in conflicting conclusions.

In view of the relative lack of information about drug effects during pregnancy, a prospective epidemiologic study was designed and implemented. The study demonstrated a workable system for monitoring an obstetric population for adverse reactions to drugs during all phases of pregnancy.

PATIENTS AND METHODS

Outpatient and inpatient obstetric facilities at the University of Florida's Shands Teaching Hospital (STH) in Gainesville were used in this study.

The inpatient obstetric unit is composed of semiprivate and ward rooms having a 28-bed capacity. The labor and delivery area consists of eight labor rooms and three delivery suites. Approximately 2,000 deliveries per year are performed at STH. Professional medical services are provided by physicians serving four-year residencies in obstetrics and gynecology and by attending physicians of the College of Medicine.

Outpatient facilities used in the study are the STH prenatal clinic and the Ocala, Fla, Health Department's prenatal clinic. The latter is one of several satellite clinics serving a 13-county area for which the Department of Obstetrics provides prenatal professional care. More than 12,000 clinic visits per year are recorded at the Shands clinic.

Approximately ten new patients were enrolled per week in the obstetric drug study. All study patients were scheduled for delivery of an infant at STH, and their conditions were monitored throughout the prenatal, perinatal, and postnatal periods by study personnel.

From the College of Pharmacy, University of Florida, Gainesville.

Reprint requests to University of Florida College of Pharmacy, Box J-4, JHMHC, Gainesville, FL 32610 (Mr Doering).

Selection of Patients

Subjects in the study were selected from those patients registering for the prenatal clinic at the STH and the Ocala Health Department's obstetric clinic served by the University of Florida. To qualify, patients must have been in their first trimester of pregnancy (14 weeks since the last menstrual period or earlier).

Outpatient Population

Patients selected for study were interviewed by a pharmacist on the day of registration for the purpose of obtaining a drug history retrospective to the estimated time of conception. Drugs used during this interval were recorded with respect to quantity and time in the gestation when consumed. Over-the-counter and prescription medications were included. During the initial interview, patients were requested to make a note, either written or mental, of any drugs consumed during the interim between visits, thus ensuring greater accuracy of return-visit interviews than that of initial screening.

During subsequent monthly return visits, patients were again interviewed by a pharmacist with respect to drugs taken since the last interview. Charts were reviewed for any notation of prescribed or recommended medications. A continuous summary was made regarding quantity and gestational age when a drug was taken. Return-visit interviews were performed each time a patient was seen in the clinic until she presented in the labor and delivery area.

Appropriate demographic data and results of routine laboratory tests were recorded throughout the pregnancy. Prenatal complications or underlying disease states during the pregnancy were also listed.

Patient reliability was assessed by the interviewer using a set of subjective criteria. Accuracy of the identification of drugs consumed was recorded. Drugs the interviewer actually saw or for which chart confirmation was available received a code for positive identification. Medications that the patient referred to by name but that were not verified by the interviewer received a different designation. Products described by the patient for which the interviewer was reasonably sure of the identification received a different code number. Finally, those drugs for which no identification was proposed were placed in a fourth category. When names of drug products taken were unknown, every attempt was made to trace the prescriber or dispenser in an effort to identify the agent. Often, calls to the prescribing physician's office or to the pharmacy where the prescription was filled provided this information. Review of medical records from STH and other hospitals provided useful information concerning previous drug consumption.

Collection of Data

Perinatal Period.—Drugs administered during the perinatal period were recorded to describe the time interval between administration and the delivery. To accomplish this, the date and time of administration of the drug were recorded and referenced in a computer to the date and time of the delivery. In this manner, the precise interval between administration of a drug and the delivery can be analyzed for possible influence of the former on the outcome of the latter. Included in this record were names of intravenous fluids, specialized drug items, routine medications, and any local or general analgesic-anesthetic agents used during labor and delivery.

In the perinatal phase, a system of data collection known as event recording was used. An observer was present during the patient's labor and delivery to make notations of the occurrence of certain predetermined, appropriately defined events, irrespective of whether the event was suspected to be drug related. Examples of events recorded include fetal bradycardia, hypotension, emesis, and meconium-stained amniotic fluid. Comparison of the incidence of a specific event occurring in patients receiving a certain drug with those who did not can be accomplished. This provides a method of screening for previously unrecognized adverse effects of certain drugs.

Newborns.—Neonates were observed for predetermined events in a similar manner employed for observing mothers. The period of surveillance included that time immediately following delivery until discharge from the hospital. Drugs administered to the newborn were also recorded during the hospitalization. In addition certain demographic data on the neonate were collected, including an accurately applied Apgar score, sex, weight, gestational age, and type of delivery.

Postpartum Patients.—Drug use by mothers after delivery was recorded by obtaining a carbonless copy of the drug-administration sheets. Medications recorded included any oral, parenteral, or topical drugs, intravenous solution, or other drugs a patient received. Patients' conditions were monitored for known adverse drug effects and events during hospitalization.

RESULTS

From July 16, 1974, to March 17, 1976, three hundred eighty-two patients were enrolled in the study. Of these, 168 patients' conditions were monitored throughout all phases of their pregnancies. Sixteen women were known to have aborted. Eight-one had not delivered their babies when the study was terminated, and 117 patients were lost to follow-up. Some moved, some were not really pregnant, some transferred to private physicians or other clinics, and some were unaccounted for.

The mean age of the 168 women whose conditions were monitored to completion was 21.9 years, with a range of 14 to 41 years. There were 52.4% single women, 37.2% married women, and 10.6% separated or divorced women. With respect to race, 55.3% were white, and 44.7% were black.

Prenatal medication consumption by therapeutic category is presented in the Table. Iron preparations are routinely dispensed to all prenatal patients. All patients consumed at least two medications, 93.4% consumed five or more, and one patient reportedly used 32 different drug products during this period. The average number of different drug products consumed per patient was 11.0. Twenty-two patients (13.1%) admitted using one or more illicit drugs during pregnancy. Marijuana was the most frequently encountered drug in this category.

Because the number and types of drugs administered to patients undergoing cesarean section vary considerably from those administered in vaginal deliveries, these patient types were analyzed separately. It was believed that more meaningful information regarding drug use in the perinatal period could be accomplished using this approach.

For patients undergoing vaginal delivery, perinatal drug administration by therapeutic class is presented in the Table. Five or more drugs were administered to 69.2% of patients giving birth by this method. Included are topical antiseptics used on the perineum before vaginal examinations and before delivery, intravenous fluids administered as standing orders, and administration of oxytocin as a routine procedure in all postpartum patients. Excluding topical antiseptics, intravenous fluids, and oxytocics, the most commonly used medications were anesthetics, either general or local. An average of 7.0 different drug products were used in the perinatal period by patients who gave birth vaginally.

Postpartum orders consist of preprinted, circle-the-number type routine medication and treatment schedules. Drug orders included those for codeine sulfate, milk of magnesia, and pento-

Medication Consumption

	Patients Receiving 1 or More Drugs From Each Class	
	No.	%
Prenatal (N = 168)		
Iron	168	100.0
Analgesics	157	93.5
Vitamins	135	80.4
Topical ointments, suppositories, douches	121	72.0
Antacids	94	56.0
Topical anti-infectives	83	49.4
Cough and cold medicines	69	41.1
Miscellaneous	63	37.5
Laxatives	63	37.5
Antibiotic/anti-infective	62	36.9
Unknown medications	44	26.2
Antiemetics	32	19.0
Barbiturate	30	17.9
Antihistamines	30	17.9
Illicit drugs	22	13.1
Intravenous fluids	20	11.9
Hormones	11	6.5
Nonbarbiturate hypnotics	7	4.2
Nutritional supplements	7	4.2
Diuretics	4	2.4
Appetite suppressants	4	2.4
Perinatal (n = 158, vaginal delivery)		
Oxytocics	155	98.1
Intravenous fluids	150	94.9
Topical antiseptics	145	91.8
Anesthetics & Adjunctive Drugs	126	79.7
Lactation suppressants	97	61.4
Analgesics	86	54.4
Sedative/antihistamines	77	48.7
Miscellaneous	18	11.4
Antibiotics	4	2.5
Postpartum (N = 168)		
Analgesics	104	61.9
Laxatives	28	16.7
Intravenous fluids	27	16.1
Miscellaneous	26	15.5
Iron	21	12.5
Oxytocics	19	6.5
Antibiotics	13	7.7
Sedative-hypnotics	11	6.5
Anesthetics & Adjunctive drugs	8	4.8
Vitamins	7	4.2
Antacids	3	1.8
Anticonvulsants	2	1.2
Lactation suppressants	1	0.6
No medications	37	22.0

barbital sodium. When discussing postpartum drug use, vaginal and operative deliveries were considered in the same group. As shown in the Table, analgesics were the most frequently used drugs during the postpartum period, and an average of 2.5 medications per patient were administered. Thirty-seven patients (22.0%) received no medications.

Neonatal drug administration most frequently consisted of only those drugs used in the routine care of the newborn. Included are silver nitrate ophthalmic solution, normal saline eye wash, and vitamin K. Antibiotics were used occasionally in the newborns.

COMMENT

A reliable mechanism for complete and accurate recording of maternal drug consumption is of paramount importance to the study of drug safety during pregnancy. The most comprehensive approach is through the use of prospective data-collection techniques, although the large study populations required to generate statistically significant values may preclude using the prospective approach. In addition to drug-consumption data, assimilation and storage of possible confounding factors occurring during monitored gestations must be accomplished. This study represents an effort to design, implement, and evaluate such a system for intensified prospective collection of data concerning the relationship between drugs and maternal and neonatal outcome.

Many similar studies in the past suffered deficiencies in obtaining maternal drug-exposure data.[9,10] Some failed to account for nonprescription drugs, and others relied entirely on chart review for obtaining information about prescribed drugs. Frequently, certain drug classes were omitted from tabulation, suggesting that foregone conclusions about the use of certain types of medications had been made.[11] When comparing drug-exposure data obtained in various studies, it is essential to scrutinize the methods used in data collection and the basic definitions employed in analysis of data. Although Bleyer et al[12] monitored patients during only the last three to nine weeks of pregnancy, their results represent the most thorough collection of maternal drug-consumption data published to date. For the purposes of our study, it was believed that all types of medications should be recorded, including vitamins, iron, and topically applied medicaments, often excluded in other investigations.

The average of 11.0 drug products per patient in the prenatal period does not accurately reflect the number of different chemical entities to which the fetus is exposed since many such products contain numerous ingredients. It is not uncommon to see prescription and nonprescription products with four or five different ingredients. When individual components are considered, actual fetal drug exposure is greatly increased.

The true risk to mother and child from prenatal exposure to drugs cannot be ascertained unless the most complete and accurate data on maternal drug intake are obtained. Preliminary tabulations of such data in this investigation suggest that the monitoring techniques employed yield a more comprehensive listing of drug consumption than previous studies.[6-8] All medications, whether prescribed or self-selected, were included. Likewise, all stages of pregnancy were considered, including prenatal, perinatal, neonatal, and postpartum periods. Thus, the overall epidemiology of drug intake during pregnancy has been recorded, allowing subsequent examination of the entire patient drug history for evidence of adverse reaction.

It should be noted that drug-use profiles vary from physician to physician and from institution to institution. The low incidence of diuretic use in the prenatal period reflects the conservative attitude of the staff obstetricians toward this form of therapy at STH. Likewise, the routine practice of administration of iron supplementation to all prenatal patients accounts for the use of at least one iron preparation per patient at some point during the prenatal period. Obstetricians in private practice may prescribe a different array of proprietary products than those prescribed by the clinic physicians in this report. Physician's prescribing habits are influenced by many factors, but the need for minimizing drug prescribing during pregnancy cannot be overemphasized. This report should serve as a reminder that pregnant women receive a vast array of prescription and nonprescription drugs, many of whose safety in pregnancy has not been clearly demonstrated.

This study was supported by contract 71-12 from the Food and Drug Administration.

Leighton E. Cluff, MD, vice-president, Wood-Johnson Foundation and former professor and chairman, Department of Medicine, College of Medicine, University of Florida, supervised the design and conduct of this study.

Nonproprietary Names and Trademarks of Drugs

Oxytocin – *Pitocin, Syntocinon, Uteracon.*
Thalidomide – *Kevadon.*

References

1. Cahen RL: Experimental and clinical chemoteratogenesis. *Adv Pharmacol* 4:263-334, 1966.

2. Lenz W: Chemicals and malformations in man, in (ed): *Congenital Malformations* International Medical Congresses, New York, pp 263-276, 1974.

3. Mellin GW, Katzenstein M: The saga of thalidomide: Neuropathy to embryopathy, with case reports of congenital anomalies. *N Engl J Med* 267:1184-1192, 1962.

4. Greenwald P, Barlow JJ, Nasca PC, et al: Vaginal cancer after maternal treatment with synthetic estrogens. *N Engl J Med* 285:390-392, 1971.

5. Herbst AL, Ulfelder H, Poskanzer DC: Adenocarcinoma of the vagina. *N Engl J Med* 284:878-881, 1971.

6. Nelson MM, Forfar JO: Associations between drugs administered during pregnancy and congenital abnormalities of the fetus. *Br Med J* 1:523-527, 1971.

7. Peckham CH, King RW: A study of intercurrent conditions observed in pregnancy. *Am J Obstet Gynecol* 87:609, 1963.

8. Mellin GW: Drugs in the first trimester of pregnancy and the fetal life of *Homo Sapiens*. *Am J Obstet Gynecol* 90:1169-1180, 1964.

9. Slater BCS: *Symposium on Embryopathic Activity of Drugs.* Robson JM, Sullivan FM, Smith RL (eds). Boston, Little Brown & Co, 1965.

10. Crombie DL, Pinsent RJFH, Slater BC, et al: Teratogenic drugs: RCGP survey. *Br Med J* 4:178-179, 1970.

11. Nora JJ, Nora AH, Sommerville RJ, et al: Maternal exposure to potential teratogens. *JAMA* 202:1065-1069, 1967.

12. Bleyer WA, Au WYW, Lange WA Sr, et al: Studies on the detection of adverse drug reactions in the newborn: Fetal exposure to maternal medication. *JAMA* 213:2046-2048, 1970.

13. Forfar JO, Nelson MM: Epidemiology of drugs taken by pregnant women: Drugs that may affect the fetus adversely. *Clin Pharmacol Ther* 14:632-642, 1973.

14. Slone D, Heinonen OP, Monson RR, et al: Maternal drug exposure and fetal abnormalities. *Clin Pharmacol Ther* 14:648-653, 1973.

15. Hill RM: Drugs ingested by pregnant women. *Clin Pharmacol Ther* 14:654-659, 1973.

Senator **Kennedy**. What can you tell us about that?

Dr. **Kennedy**. Senator, the way we read the Florida study, and the general trends, is that although a significant number of drugs are still being employed during pregnancy, that increasingly these are related to the therapeutic needs associated with that particular problem, and that the use of drugs for unrelated conditions during pregnancy is declining, just as the use of diagnostic X-rays during pregnancy has declined.

We think that education is making some impact on that use.

A good deal of the drug use reported in the Florida study are related to special needs during pregnancy, the provision of extra iron, for example. I think it would be correct to say, however, that no firm national use figures on drugs during pregnancy are available that give really quantiative information about the extent of that decrease. As a result, I think we do need to know a lot more about drug use during pregnancy.

Senator **Kennedy**. We have, besides the Florida study, the Jaffe study, professor of pediatrics and pharmacology, University Pennsylvania, where he points out, on page 6, that the pattern of drug use, when compared to the study conducted in California prior to the Thalidomide episode demonstrates drug consumption during pregnancy has certainly not decreased as a result of that event.

We saw an 18 percent of barbiturates, and 18 percent antihistamines in Florida.

Maybe you can just make a comment about the use of drugs, the use of alcohol, the use of smoking during that period of time, and your own concern about it.

Dr. **Kennedy**. Well, we had tremendous concern about it. As you may know, I testified before Senator Hathaway some weeks ago on the subject of alcohol use. We think that should be as strongly discouraged as one can possibly discourage it. We also think that drug taking for purposes unrelated to pregnancy, particularly during the first trimester, where a number of very sensitive developmental events are taking place, is to be discouraged.

As I will testify later, we have learned things about diagnostic X-rays during pregnancy that has caused our Bureau of Radiological Health to begin to take steps to restrict those exposures.

I think it is fair to say, Senator, that given what we know about teratology these days, given our appreciation for the sensitivity of the developmental events that are taking place, particularly in early pregnancy, that the greatest possible cautions should be exercised in the use of drugs during that period.

Senator **Kennedy**. You are talking about all drugs now, not only prescription, but over-the-counter drugs?

Dr. **Kennedy**. Yes.

Senator **Kennedy**. That the women of this country who are pregnant should take the least possible, consistent with other health needs, is that your message?

Dr. **Kennedy**. Yes; I think that is certainly consistent with what has happened in the evolution of FDA labeling, for such drugs.

I will be pointing out in my testimony the various occasions where we have narrowed labeling indications, and attempted to eliminate such uses.

We do not know exactly what the causality relationships are, but accompanying these improvements that I just ticked off for you such as the education of physicians and patients have markedly decreased maternal mortality and infant mortality.

As you pointed out in your opening statement, the reduction has been dramatic, but it has not yet propelled the United States to the forefront of the world's civilized nations in terms of infant mortality. It is not easy to explain exactly why that is so.

I think that in some other nations there are stronger emphases on preventive care, on prenatal nutrition of the mother, on various factors of that kind, that may project them ahead of us in that particular statistic.

It is also the case that compared to some of the medically advanced Western nations, the United States has a more diverse population, and as you and your subcommittee well know, we have not been as successful as we ought to be in extending the best in health care to all of the segments of that population.

But even if you use as your comparative indicator the white middle class in the United States, it still, as I understand the matter, puts us only about fifth. And so one has to look elsewhere than to maldistribution of the best of health care in this country to reach a complete explanation of that phenomenon.

I think despite the significant recent gains in the quality of obstetrical care, we are nonetheless confronted by a disturbing paradox. The very techniques and products that have helped improve prenatal care and decrease infant mortality have themselves raised new questions. Useful drugs—such as anesthetics to relieve pain and oxytocins to advance labor—can, when misused or overused, result in increased risk to the patient and distress to the fetus. Beneficial techniques for monitoring fetal development—such as ultrasound—could, if misused, prove to be the agents of subtle, long-term pathological effects. Although I would emphasize there is not evidence now from long-term studies of low doses that ultrasound in particular produces a problem, at least in its use at the time of parturition.

As I will testify later, we think the matter does need and deserve attention, and we are trying to see to it that it gets it.

Senator **Kennedy**. Just on this, you use the words "if misused"—that is really part of the key to the whole issue that we are considering this. What is misuse and what is appropriate use and how do you know what is appropriate use if long-term kinds of reviews or studies in terms of some of this technology had not been done? This is part of the issue which we will be taking a look at this morning because what we really want to know is what is appropriate use. You probably cannot tell it is being misused unless you know appropriate use. You cannot tell appropriate use unless you are able to get, I would imagine, some rather clear information or data or evaluation of both technology and health education.

Dr. **Kennedy**. I would certainly agree. You cannot know a benefit to risk ratio unless you know the numerator and denominator.

I think what you are saying is until we know a little bit more about the long-term risks, it is very difficult to decide what appropriate use is. I guess my response is that what a failure to know the risks fully suggests is that we proceed with great caution, and at least we delete those uses, for example, in basic monitoring techniques in every case where there is not clear evidence that they are needed and effective.

At the very least, if we do not know the risks, we can eliminate those uses that provide marginal or nonexistent benefits.

Senator **Javits**. Will the Chair yield?

Senator **Kennedy**. If I can just finish this point.

Senator **Javits**. Sure.

Senator **Kennedy**. On the question of numerator and denominator, we really cannot say with great certainty what that numerator and denominator is. As I gather, you advise caution certain about the use, without knowing numerator and denominator. We have not got the information today to measure, as I understand it, that numerator and denominator.

Dr. **Kennedy**. I think I have perhaps strained my metaphor so far to make it a little difficult to talk about generally.

If we take risk to be the denominator in the case, for example, of long-term sequelae to the use of ultrasound in monitoring, we do not know what the denominator is. We know that for various applications we will have various benefit numerators. OK?

What I am suggesting is when we think the denominator is small we ought not use procedure unless the numerator is pretty big.

Senator **Kennedy**. I think what we are faced with now is we have widespread use of technology and procedure, and that is what you are cautioning us against, and it may be appropriate use even with information you have available now, it may be extremely urgent and terribly important in terms of the health implications for the infant and for the newborn. But what you are cautioning us against is widespread use of the technology unless we have some pretty clear definitions of numerator and denominator.

Do I understand your position?

Dr. **Kennedy**. Yes. Certainly there should not be widespread use in the absence of clear definitions of the benefit. I do not know how hard our information is here, Senator, but my judgment on ultrasound question is that the use is so widespread that one can infer that it may be a little uncritical.

Senator **Kennedy**. And you caution against this?

Dr. **Kennedy**. Yes.

Senator **Kennedy**. Because of the failure of being able to at least draw up those parameters——

Dr. **Kennedy**. I would certainly caution about it in cases where there is not clear indication that it provides a benefit.

Senator **Kennedy**. But if you have widespread, is can be indiscriminate then, can it not——

Dr. **Kennedy**. Yes; it can be.

Senator **Kennedy**. If you have a requirement that says every hospital has to have it or something on every patient, that would be going further than you would be prepared obviously to go?

Dr. **Kennedy**. Yes; it certainly would.

Senator **Kennedy**. That is the case in several hospitals.

Dr. **Kennedy**. I understand there is a proposal to that effect. I am not aware, in my own knowledge, of places in which that particular kind of monitoring is provided for all cases. But my knowledge on this point is not very extensive.

Senator **Kennedy**. Well, George Washington Hospital is one of them, and there are other hospitals. But I think if that is the case, which we believe that it is the case, we ought to be aware of it.

Senator **Javits**. I just wanted to make the point that what induced me to call for these hearings, and Senator Schweiker who is ranking member who we have designated for this committee, is the indiscriminate use, because there is a certain fashion in medicine, we all know that—ladies like to go to the doctor, and it is going to make it easy and even going to find a timetable so that they can get to the church on time. That is what really worried me. It extends not only to ultrasound techniques which are, after all, in the course of delivery, but it extends to drugs, pain killers, to rather quick use of cesarean section, and trying to reduce the pain of childbirth itself. All of these things I hope very much we will look into because, as I say, it just gets to be fashionable to go to the obstetrician to deliver the baby on time and with the least discomfort, although that may be the worst for the baby, and it is also worst for the mother.

I have no preconceptions. My lead in was high mortality rate in the United States considering the rest of the world. And from knowledge of Park and Fifth Avenue doctors, and why people go to them, this goes to the highest economic levels of the population—if a woman is rich, it does not mean she cannot have a malformed or otherwise difficult child which may develop years later. Those things I hope very much you will be able to help us to be enlightened on.

This is not a witch hunt; to the contrary, I am very grateful for miracles of U.S. medicine. But this hearing is an effort to raise public attention and disclosure of the facts.

Thank you very much.

Senator **Kennedy**. Commissioner, on the hospitals, in our review we found Johns Hopkins is 100-percent monitored; George Washington 100 percent; Greater Southeastern Memorial, Washington is 100 percent; Indiana University, Indianapolis, is 80 percent; Hopkins County, Madisonville, Ky., 80 percent; University of Minnesota, Minneapolis, 80 to 85 percent; Sunrise Hospital, 100 percent; Columbia Presbyterian, New York, 100 percent; St. Luke's Hospital, Aberdeen, 100 percent; Women's Infant Services, Providence, R.I., 100 percent; Arlington Hospital, Arlington, Va., 90 percent; University Hospital, Seattle, 90 percent.

This is just a survey that was done by the committee on taking hospitals at random actually, and the other percentages, the others are significantly high.

I think this is the point which hopefully has been made as a result of these exchanges about your own concern about widespread use. Obviously there may be extremely important appropriate use for that technology, but you are cautioning about just widespread use until we have a clear understanding of the potential risks?

Dr. **Kennedy**. I agree.

I was next going to point out a few of the problems that attend the design and execution of studies that predict the effect of drugs and devices on the fetus. I just wanted to point out, Senator, that this is a troublesome area.

Teratogenicity is plagued by species-to-species variation; no single animal model can be relied on as a foolproof predictor of human fetal effects. And although dramatic adverse effects of a drug on the fetus may be discerned through careful epidemiologic search—as with the anomalies resulting from Thalidomide—adverse effects involving fetal death or subtle malformations may go undetected for sometime. Minor anomalies often occur without any history of drug exposure; these represent a "background" against which drug effects are difficult to recognize. Delayed effects, even when they are striking, may escape detection until exposure is quite widespread—as with the "DES daughters."

Although epidemiology studies are thus limited, they sometimes produce extremely useful scientific data for regulatory decisionmaking. More such work is needed to help weigh the benefits and risks of a wide variety of drugs and devices. A national effort of the proper scope will require a much greater commitment of resources and effort than we have heretofore been willing to make.

These scientific problems are difficult enough. But they are made even more refractory by ethical questions involving the use of human test subjects. We discussed that earlier in a response to a question you asked. We restrict the exposure of pregnant women to such tests. We think it is a sound policy in view of the vulnerability of the fetus to harm from drugs which cross the placulental barrier; it does have the consequences of depriving women who may be pregnant from undertaking some forms of therapy. In short, our concern for the rights of subjects may collide with a broader set of patient rights. It is not easy to define a "fair" solution.

Senator **Kennedy**. As we go to the drug area, what we have seen before this committee over the period of the last 5 years, I think we did the first hearings on the DES issue, and we have done work also on the premarin factor, and we have seen at least in dramatic illustration before this committee where drugs have had implications far, far after they were—these instances are 18, 15, 20 years—after they were declared as being safe and efficacious. That, obviously, is the kind of examples that we want to try to the best we can, we are not going to be able to do it absolutely, but to avoid obviously in the future, and in the drug area we have seen where it has not been a hypothetical risk, but a real one. That is obviously what we are concerned about.

Dr. **Kennedy**. As you know, FDA is primarily responsible for assuring that marketed drugs and medical devices are safe, effective, and properly labeled. To help physicians and users deal with the problem of drug use in pregnancy, we have imposed labeling requirements on drugs that may be used during pregnancy. Certain drugs have carried cautionary statements about the lack of information regarding fetal effects, and about the results of animal and human experiments where these were available. We shall continue to rely heavily on professional and patient labeling to minimize the use of unnecessary medication during pregnancy.

We cannot assure that drugs and devices are properly labeled, and that physicians and patients are informed of risks and benefits, without monitoring the safety and effectiveness of marketed drugs. The monitoring of drugs and devices used during pregnancy labor cover three major categories of use—the diagnosis of pregnancy, treatment during pregnancy, and treatment during labor and delivery.

In the past, various sex hormone preparations have been widely used for pregnancy diagnosis. They consisted of estrogen-progestin combinations, or of progestins alone, that produced withdrawal bleeding in patients who were not pregnant.

Recent reports have indicated that the use of sex hormones during early pregnancy may seriously damage the offspring. They suggest an association between hormone treatment and such congenital anomalies as heart defects and limb reduction.

We have concluded that the potential risk of teratogenicity argues against the use of sex hormones as a diagnostic test for pregnancy. Their use is also made unnecessary by the general availability of safer and more effective biological and immunochemical tests for pregnancy. Drugs used for this particular indication have been removed from the market and the labeling for all progestational drugs has been revised so that diagnostic tests for pregnancy are listed as contraindications.

As I noted earlier, estrogens—particularly diethylstilbestrol—were widely used beginning in the 1940's for the treatment of threatened and habitual abortions. There is now considerable evidence that such drugs are ineffective for this indication; and DES has been shown to be associated with a delayed risk of vaginal adenocarcinoma in female offspring. Because this study is likely to apply to all estrogenic products, the labeling is now required to list "pregnancy or suspected pregnancy" as a contraindication for the use of all such drugs.

Progestational drugs also have a history of use in the treatment of threatened and habitual abortion. The evidence we have does not show that progestagens are effective for this indication; but, on the other hand, their use may be associated with an increased risk of congenital anomalies. The agency therefore requires that progestational drug labeling carry a warning against use during the first trimester of pregnancy.

Thiazide diuretics have been used widely in the past in the management of edema—swelling caused by excess water retention—associated with pregnancy. The use of diuretics during pregnancy was considered at an open meeting of FDA's Obstetrics and Gynecology Advisory Committee and, as a result, a series of labeling changes have been made for such drugs. These changes emphasize (1) that edema during pregnancy is very common, and usually needs no treatment other than supportive measures; (2) that diuretics do not prevent the toxemia of pregnancy, nor treat it effectively; and (3) that the routine use of diuretics exposes mother and fetus to unnecessary risk. In addition to making changes in the labeling, the agency has also treated this subject in a "Drug Bulletin" article.

Many pregnant women still receive drugs—both prescription and over-the-counter preparations—during the early stages of pregnancy for such minor conditions as colds, coughs, nervousness, anxiety, and other ailments for which the use of such drugs cannot be considered absolutely necessary.

We are happy to say—at least as we perceive the attitude—that women are developing a healthy skepticism about the use of drugs during early pregnancy.

Media attention to the possible adverse effects on the fetus of certain drugs taken in the first trimester have increased, and most physicians have become highly selective in prescribing medication during the first trimester of pregnancy. Although this has cut down considerably on the number of drugs being used, some unnecessary use of drugs for minor conditions remains. Some of these drugs have been around for a long time, but have not been tested adequately for teratogenic effects.

Here I would emphasize that adequate testing in the case of teratogenesis, particularly as it applies to animal tests, is a very different matter from adequate animal testing with respect to carcinogens. We have a lot more confidence in the degree to which animal models predict human difficulties in the case of carcinogens than we do in case of teratogenics. You may recall that Thalidomide does not come up positive in tests on conventional laboratory animals. There are many other examples of that kind of experience, and you simply cannot say just because you apply an agent in experimental animals and it comes up looking clean in terms of producing difficulties in embryonic development, that it will be the same way for humans.

The pattern of early development shows a lot of species-to-species variation, and it is an area in which we have more trouble than in any other in going from animal data to human data.

Senator KENNEDY. The fact is, you have about 25,000 prescription drugs, 300,000 over-the-counter drugs. Of course, those are not tested in any way for their impact during a very delicate time, the first trimester during pregnancy. What can you tell us about that? We do not want to unduly alarm people that need those particular kinds of drugs for certain kinds of treatments, but you have to say that there really has not been the kind of review on those to give the consumer the absolute signoff in terms of the impact to the effect it might have on the fetus?

Dr. KENNEDY. Well, yes, we can do some things about that, Senator. Let me list them, but say in advance that the total picture is not yet by any means satisfactory.

First of all, for drugs that are deliberately intended for use by women early in pregnancy, we can require animal studies, and we will——

Senator KENNEDY. Is that not rather small? That is just a handful.

Dr. KENNEDY. That is right. That is a small fraction. In newly proposed labeling requirements for all drugs, there is going to be a section on use in pregnancy where we summarize the results of animal and human studies on teratogenic effects to assist in benefit-risk decisions. Based on such studies, certain drugs will be contraindicated for use during pregnancy, whereas we may permit the use of others.

Senator KENNEDY. How many fall in that category?

Dr. KENNEDY. I think until we complete the labeling requirements, I do not think we can give exact numbers.

Dr. FINKEL. There will be, from our current information of drugs that have been studied, animal tetratogenic studies—most drugs do not turn out to be positive. So that there would not be any absolute contraindication unless we have some human data which would contraindicate the use. In most cases, there will be warnings or precautions that the drug should not be used unless absolutely needed.

Senator KENNEDY. How many are we talking about? That is in numbers. There is only a handful that are actually prescribed, as I understand it, in terms of dealing with pregnancy now. How many others—what are the numbers that we are talking about? We have 25,000 prescription drugs, 300,000 over-the-counter drugs. A variety of these are being taken in differing quantities and different mixes by people. What percent of the prescriptions are you actually studying?

Dr. **Finkel**. Well, all the newer drugs that have been studied in the middle 1960's and beyond have gone through the animal screening studies. So that we have information on those to give the physician for whatever——

Senator **Kennedy**. How much human data on pregnancy——

Dr. **Finkel**. Not too many.

Senator **Kennedy**. Are we talking again about 10 or a 1,000 or 10,000?

Dr. **Finkel**. No. We may be talking about 100.

Senator **Kennedy**. A hundred out of 25,000 approximately?

Dr. **Finkel**. Yes.

Dr. **Kennedy**. As you know, the FDA advisory panels are also doing a large scale review of safety and efficacy of over-the-counter drugs on ingredient-by-ingredient basis, and they have been and will be continuing to make recommendations about labeling for use by women who are or who may be pregnant. We are also developing and will eventually require patient information for most prescription drugs. These leaflets will provide patients, in lay language with information about the potential risks of drugs taken during pregnancy.

FDA's new labeling regulations provide a cautionary note on the administration of drugs to nursing mothers. This information will also be conveyed to the patient in the patient leaflet. Most drugs taken by lactating women can be excreted in maternal milk and, therefore, ingested by the nursing infant. The long-term effects such exposure are largely unknown.

The Department of Health, Education, and Welfare issued an official health caution last summer, warning that heavy use of alcohol by pregnant women may result in "fetal alcohol syndrome," a subject on which I testified to Senator Hathaway's subcommittee some weeks ago. We have a plan to label new drugs that contain alcohol with respect to this hazard, and some of them actually contain significant amounts. We hope that warning labeling on alcoholic beverages for this particular problem will also result from the proposal recently offered by the Bureau of Alcohol, Tobacco, and Firearms of the Treasury Department.

I would like to turn, if I may, to the question of ultrasound which you raised in your initial statement and which we discussed briefly.

An increasingly common exposure during pregnancy is to ultrasound. This technique is widely used during pregnancy to detect, visualize and monitor the fetus. Among other things, it enables the physician to determine fetal age, to detect pregnancies outside the uterus, or to diagnose fetal anomalies.

Studies of the effects of ultrasound exposure on the human fetus in utero have thus far yielded inconclusive evidence. Although no increase in infant abnormalties has yet been observed, adequate studies to detect anatomical abnormalities have yet to be performed. Neither can conclusions be drawn about delayed effects.

Some scientists believe that the efficacy of ultrasound and other fetal monitoring has not been thoroughly evaluated, and benefits should therefore not be assumed. According to a recent study, the use of ultrasound to locate the placental for amniocentesis does not appear to reduce material complications, and electronic monitoring of fetal heart rate—which can be done ultrasonically or by other means—appear to result in the increase use of cesarian procedures without a resulting improvement in outcome.

To help resolve questions about the long-term effects of ultrasound, FDA is conducting a study under contract with the University of Colorado to determine whether children exposed 8 to 10 years ago to diagnostic ultrasound in utero differ from an unexposed, otherwise similar, group of children. These children will be followed for the next 3 to 4 years to determine general health, physical and intelectual development, and neurological function. This study is largely exploratory, and should provide a basis for detailed followup and testing.

I would emphasize design of the study is not the kind that I think will yield the most sensitive measures of those outcomes. I would prefer to do prospective rather than retrospective study for that purpose. We think it would give us a pretty good indicator of whether there is a problem there and whether we should design a major prospective study to evaluate it.

Senator **Kennedy**. This is, as you mentioned, Mr. Commissioner, in your own testimony that it is a procedure widely used, and our surveys show that as well. There have been some storm signals, or at least questions which have been raised over the period of years, going, as I am sure you are familiar, with recourse to the Bureau of Radiation and Health, now part of your Division of FDA, in 1970, which points out the current state of knowledge concerning biological hazard of ultrasound in light of projected expansion in the use of ultrasound. And this is a matter of great concern given the intense exposure for sufficient periods of time.

[Senator Kennedy read from 1970 study, 1977 study, and Symposium on Ultrasound in 1977.][1]

Senator **Kennedy**. Any fair review of those studies, I think, points to the conclusion which would sound a very important cautionary note.

On the other hand, you have statement of policy by the American College of Obstetrics and Gynecology, which says that this diagnostic service should be available to all obstetric patients.

That is approved by the executive board, May 1975.

This is what the academy points out: Dangers of monitoring, external monitoring, the dangers to fetus on mother secondary to external monitoring with ultrasound are only theoretical. Presently there is no evidence to suggest that ultrasound is deleterious to the fetus. Therefore, external monitoring is safe and it provides initial assessment of a pregnancy provided that the limitations are understood.

Those are interesting words there "since there is no evidence to suggest that ultrasound is deleterious to the fetus, therefore external monitoring is safe."

It provides initial assessment.

---

[1] The material referred to may be found in the files of the subcommittee.

So you have, as I see it, the various studies of the groups over a period now of 7½ years which have raised questions. You have the other statements of the particular academies that are dealing most closely with it and are urging that there be an expansion of this program.

We have seen the result in just our survey of the dramatic increases in this by a number of the hospitals.

You have your own cautionary kind of factors, statements on this issue, and I am just wondering where this leaves us.

I suppose the real question is what the practicing physician is going to do with this, let alone all the other kinds of problems of cost, malpractice insurance and other factors which are important, and obviously are secondary to this issue.

Dr. **KENNEDY**. I am not, as you know, Senator, medically qualified, and so talking on the benefit side of monitoring is something I have a little bit of difficulty with. I do know some things about animal studies. If I might just take 30 seconds to say a little more about those.

Most of the studies referred to in the statements that you made earlier do, I think, involve rather higher energy exposures than are normally used in monitoring during terminal stages of pregnancy. However, some animal studies have demonstrated increased incidents of fetal deformities with rather low level ultrasound used earlier during development. There is every reason to believe that the fetus would be more sensitive to any of the adverse effects that might be associated with ultrasound if it was delieverd early during pregnancy.

There is some disagreement among people who have evaluated the evidence about whether fetal effects due to ultrasound might be involved instead of some more direct action. I myself find that distinction a little academic. I am terribly interested in it, but if it produces teratogenic effects, then I am concerned about it.

Senator **KENNEDY**. If I might just interrupt you here. I think what I have gathered from the statements is that you are rather cautionary about the use of this type of technology. I think what we would be interested in, if you would take a review within FDA is if you have authority under the medical device legislation. I do not think we can expect you to give us an off the top assessment, unless you desire to do so.

But it seems to me that you ought to try and at least get somewhat definitive, a definitive kind of review or study, and to find out in terms of that particular technology, which is getting increasingly wide and broad use today.

Dr. **KENNEDY**. Senator, I will be glad to do that. I guess what I was going to come to in my rambling way was that the animal studies give us some caution for concern, but nothing very definitive. We hope epidemiological results will give us something clearer, but there is certainly nothing to justify statements like the one you recited at the end of your last remarks. Our favorite is: "Ultrasonograph can be safely employed at any time during pregnancy." That is from the textbook on current obstetric and gynecologic diagnosis and treatment.

I am troubled that the impression is getting around that this monitoring technique is known to be without risk. In fact it is not known to be without risk, and I think that point should be understood.

Senator **KENNEDY**. That is clear discrepancy, because those that have in the medical profession perhaps greatest responsibility are putting out in their publications a statement which is dramatic or significantly different from what you state. That is part of the dilemma. They state: "Presently there is no evidence to suggest that ultrasound is deleterious to the fetus."

I would think that is another way of saying it is without risk. At least I think the message is getting across to the doctors that therefore external monitoring is safe and it provides initial assessment for pregnancy provided limitations are understood.

That is different from at least both the tone and comment in the statement you are making here. Those are the inconsistencies and the basis for your kind of comment and statement and caution have been illustrated in those series of studies that have been done by various groups.

We are getting that kind of inconsistency. I suppose the consumer is asking: Better listen to the doctor or do they listen to you?

Dr. Kennedy. Well, I think that the problem here, as always with unevaluated risks, is that somebody is always prepared to minimize them and others are prepared to be more cautious. My own view is that in general one should be cautious. I am not trying to tell individual physicians whether they should recommend monitoring in an individual case. I am only trying to suggest that because the risks are unknown and because there is reason to suggest that there might be some risks, a cautious physician would want to be reasonably well assured that there was some benefit to the procedure. That means it seems to me not making blanket assertions or blanket requirements for this kind of monitoring, but investigating each case, examining the merits, the needs in each case, and making a careful and conservative decision about it.

Senator Kennedy. Clearly a policy that requires some hospitals—that they be required in every case—is not a correct one?

Dr. Kennedy. I would think that is not a wise policy, Senator. We are meanwhile working on three programs to reduce what risks may exist: (1) development of methods for the measurement of ultrasound intensity emitted by commercial equipment; (2) a quality assurance program to study the image quality of diagnostic equipment; (3) improved training opportunities through liaison with the professional societies; and (4) coordination with manufacturers and professional associations in the development of voluntary equipment standards.

Our view of the problem is quite simply until we know more about the risks, if any, at least we had better do everything we can now to minimize the exposure and to make sure that a given exposure produces the maximum useful diagnostic result.

I might briefly mention another matter because there are respects in which it is parallel. We have been active recently in developing programs for reducing radiation exposure in the course of use of diagnostic X-rays. I am submitting for the record a brief summary of our recent activities in this area because we think it is an important program that has led to an overall decrease in the medical risks that are encountered by the fetus.

Finally, I would like to talk to the matter of labor and delivery.

As you know, the relief of pain in labor presents special problems. The respiratory center of the infant is highly vulnerable to sedative and anesthetic drugs, and their misuse may jeopardize neonatal respiration. This consideration is more than a mere theoretical possibility:

sluggish respiration is a frequent sequel to birth in infants whose mothers have received sedation during labor.

Because no completely safe method of pain relief in obstetrics has yet been developed, it is sometimes asserted that the hazards of pain relief in labor exceed its advantages. Considerable experience, however, shows that obstetric analgesia and anesthesia, when judiciously employed, are usually beneficial rather than detrimental to the mother; adverse effects upon the infant are not usually a serious problem. The commonly employed analgesic drug meperidine—Demerol—has been criticized because no controlled experiments have established that its use is free of effects on the infant. Demerol, like other narcotic analgesics, causes mild respiratory depression in some cases. But when the drug is used judiciously, the depressing effects are usually reversible by modern resuscitating techniques and counteracting drugs, Long-term effects have not been adequately examined, and epidemiological studies are badly needed.

Senator JAVITS. Are you planning to make them?

Dr. KENNEDY. Excuse me?

Sentaor JAVITS. Is this your plan to make these epidemiological studies respecting this particular matter? You say they are badly needed. Is there anything going?

Dr. KENNEDY. I think the problem, Senator, is this: Nobody quite knows how to do an epidemiological study on any kind of modest scale on this problem because, as you know, pregnant women receive a variety of different drug exposures often even during normal delivery. It is difficult to design an experiment of modest size that can test out this particular variable. If our people knew a way to design such a study, or if somebody had a design for such a study that seemed likely to yield a clear result, I think we would be anxious to support it.

But my understanding is that no prospective design has been worked out that would really answer this question.

You might well then ask: Why did you say that epidemiological studies are badly needed?

I guess my answer is that I think some very large-scale studies can be undertaken on pregnant women, studies of a scale not heretofore considered seriously that might resolve this problem, because one way of testing a part of multivariable situation is to get the numbers up to where you can start to do some very fancy statistics.

Senator JAVITS. Have you invited the medical profession to give you its ideas on these studies?

Dr. KENNEDY. Well, I think the correct answer to that question is that our advisory committee in this area has probably considered the question, although I do not have chapter and verse on it. I will be glad to supply that for the record.

In developing initiatives in the whole area of epidemiology, I suspect that FDA and the other agencies of the Public Health Service will probably be asking for advice on what kind of epidemiological studies in this area are needed. It would certainly be usual for us to reach out for that advice.

Senator JAVITS. But the balance of your judgment is in favor of continuing use, notwithstanding the absence of study? That is the decision you are making by essentially what you are saying? You need study. You cannot make it. You do not even have a plan for it. I am not being invidious about this. It is just stating a fact. You think it should go on, the use of it, subject to a later period.

Dr. **Kennedy**. My understanding from our Bureau of Drugs, Senator, is that there are a number of problems that are encountered for which no really good alternative is available. What we would be doing essentially is risking a host of complications due to absence of an adequate drug of this kind in both mothers and the fetus on the basis of a concern that we do not yet understand enough about. So, my answer to your question is yes. The preponderance of the evidence suggests that there are at least some indications for which the drug should be available to physicians. Now, of course that only starts to describe the problem. Because as you know, once we make the decision that there is a limited set of indications for which the thing is appropriate, we run the risk that it will be prescribed outside that zone, and that of course is beyond the reach of our regulatory control, perhaps appropriately.

But we do think that physicians should be aware of this concern, and we would hope that the use of the drug is limited by wise judgments of practitioners.

Senator **Javits**. Mr. Commissioner, I am not a believer in running no risk. I think the American people have been deprived of many drugs which are useful to them simply because there seems to be a philosophy that there cannot be the remotest scintilla of risk. That is not true in life. There is no reason why it should be true in drugs.

The minute you walk out the door in the morning or the evening, most accidents happen at home the minute you get out of bed. I am inclined to agree with that. I just wanted to get the facts down to record. We have got almost an obsession with the idea that the slightest indication of risk, especially if the word "carcinogenic" can be attached to it—that is the end of that.

I think your job is—that is why I am saying it to you—is to give us just a value judgment which you are making in this matter and which I welcome.

Senator **Schweiker**. Mr. Chairman, I would like to ask the Commissioner a question. I understand there was a collaborative paranatal project done by NIH from 1959 to 1965 which might well have focused on the effect of drugs. Would that not be a basis for information in this very area, just to follow up the project that was done back then?

Dr. **Kennedy**. Could I ask Dr. Finkel's help in this. She is aware of a Bureau effort in this area.

Dr. **Finkel**. Those data have been published in a book and we have perused the book for any evidence of potential risk. The study was not large enough in most cases to exclude a risk. And where there is a suspicion of a risk, we intend to ask for additional studies to try to evaluate that.

Sentor **Schweiker**. Are you saying that we are doing followup studies on that study now?

Dr. **Finkel**. Yes; the book was published last year, and we have reviewed the data. In most cases there was no evidence, based upon the size of the sample, that the drugs that were studied resulted in a risk of congenital anomalies. In some cases there is a suspicion, and we do not know whether it is because the study was too small, and suspicion just was raised and it might be spurious, or whether there is really an association. In those cases we are going to ask for additional epidemiologic studies.

Senator **Schweiker**. Do you know offhand what kind of drugs were studied in that particular study or not?

Dr. **Finkel**. Large numbers of drugs. Drugs from all classes, drugs that are used for pregnancies and drugs that are incidental to pregnancy for diseases which just happened to occur during that time period.

Senator **Schweiker**. Then it should be a helpful guide, except for size in terms of statistical probabilities, is that what you are saying?

Dr. **Finkel**. Yes.

Senator **Schweiker**. It should certainly give us some indication of trouble, even though those statistics may not be reliable, would it not?

Dr. **Finkel**. Yes.

Dr. **Kennedy**. Senator, if I can just add one thing to that. I think the problem that troubles many people, and it is my understanding that it is not addressed particularly in this study, is that you would like to see some long-term follow up of infants that did experience respiratory depression as a result of their mothers taking meperidine just before parturition on the hypothesis that possibly respiratory depression and associated events in the central nervous system could produce more lingering effects. There again I think a prospective epidemiological study or retrospective one of it can be adequately designed would be a good thing to do. In the meantime we have required Demerol labeling telling physicians that its safety in pregnancy has not yet been established and that as an analgesic during labor it may have adverse effect on newborn, respiratory depression, and its labeling says that.

Senator **Kennedy**. I think we have covered most of the remaining testimony with the exception of the elective induction. You may want to comment on that.

Dr. **Kennedy**. I was going to point out that oxytocic agents—drugs which stimulate the uterus to contract—have been used for many years to advance labor and to decrease postparturient bleeding. There is a growing consensus among obstetricians that elective induction of labor—done for the convenience of the patient or physician—is undesirable because the fetus is placed at greater risk, especially where the monitoring of induction is not optimal.

Senator **Kennedy**. You are not going to be surprised if we hear this morning that it is widely done?

Dr. **Kennedy**. No; I am aware of that, Senator.

Senator **Kennedy**. Do you see any circumstance when it is done for convenience of the patient that it would be medically justified?

Dr. **Kennedy**. I think a strictly convenience indication is probably not ever an adequate indication. That is at least the conclusion of our Obgyn advisory committee which has recommended that elective induction of labor should be deleted as an indication from the labeling for oxytocic drugs because the benefit-to-risk ratio cannot be defined at this time.

The committee also recommended that where they need to be used, they should use a particular route of intraveneous administration. They should be administered by an automatic infusion pump or other such device for safe administration and that the patient's labor should be monitored at least with the use of an external fetal electronic monitor.

The consensus of the committee was that in particular diagnosis where it was needed for reasons other than convenience that this means of induction of delivery be taken.

Senator **Javits**. Would that be accomplished by the action respecting the labeling because that would be simply passive. It would be eliminated, so what? If they think it risky, do you think there should be some affirmative indication——

Dr. **Kennedy**. I think so. I should point out, Senator, we are having a public hearing on the recommendations of the advisory committee. It is a controversial one. There are some physicians of great capability that are prepared to argue the other side of this one, and we think we ought to have both sides.

A narrowing of physician labeling is about all we can do in this particular case.

As you know, we would withdraw the drug entirely only if there were no indication, no patient population, in which its benefits exceeded its risks.

But, in fact I think it is everyone's view that under some conditions this is necessary.

Marion, you may want to define what those conditions are. I do not know them. Certainly the advisory committee sees it that way and therefore if FDA feels it is in the public interest to keep the drug available, yet wants to discourage its use for particular indications, we essentially have two weapons at our disposal. One of them is narrowing the labeling for the physician so it says do not use it for *x*. The other one is publicizing that fact through our Drug Bulletin which goes to just about every doctor and health professional in the country. We think it is read widely. We do not regulate the practice of medicine so we cannot stop it from being prescribed in some cases for that purpose.

Dr. **Finkel**. Indications for induction, medical indications, include certain diseases like toxemia of pregnancy, which is a serious complication of pregnancy, diabetes is another indication; premature rupture of the membranes in which labor needs to be precipitated because of risk of infection.

Senator **Javits**. What I had in mind for both of you is whether or not the labeling should say anything affirmative. That is all. I am only inquiring of your practices—I am interested in learning how you feel about it. In other words, should you eliminate the issue from the labeling, the doctor has a right to assume if it is not there, it should not be used indiscriminately for the purpose—is there any case or are you going to consider one where affirmative labeling such as do not use this in normal cases because that goes to the thing I told you about before. Most people in this country are not poor. Only 15 percent of our country are in the poor range. Eighty-five percent are middle class or upper economic class. They all go to doctors. This is a big attraction for obstetricians that we will do it on time, if you have to go to a ball, go, and tomorrow we will have you in the hospital.

That is why I ask this question. This is an issue of public enlightenment and control which may be desirable beyond the negative, to wit, strike it out of the labeling?

Dr. **Kennedy**. No. Senator, I have misled you a little bit. It is in fact affirmative declaration. When you list a counterindication in physician labeling, it says: Don't use for *x*.

Senator **Javits**. Wonderful. That is all I have.

Senator **Schweiker**. I would like to follow up on one of my questions because there seems to be a question of whether the data are available.

I would like to go back to Dr. Finkel. I understand the study I was questioning you about cost $150 million. A $150 million study ought to have had an appropriate sample size. I understand that even though the study was done in 1959–65 time frame that the data has only recently become available. I also understand there are a lot of data that are still in the computer.

It just seems to me with all those conditions here, with $150 million investment, we have a pretty good reason to try to go in and ascertain at some expense the status.

I realize this is an NIH study. So I do not want to come down too hard on FDA. It seems to me here is an awfully good place to start, if we have already invested $150 million. Maybe Dr. Finkel would like to add something.

Dr. **Finkel**. If I recall, I think there are 50,000 patients in the study. Not all of them received the same drugs. Some of them did not receive any drugs. So when one is looking for a data base on a particular drug, one may not have more than 1,000 patients, 3,000 patients, depending on how popular the drug is that was used during pregnancy.

So that one can determine a relative risk in that particular size patient population. But it does not mean that there would be no risk, let us say, if 10,000 people had taken the same drug. So there is this limitation.

Senator **Schweiker**. I recognize the limitation. I understand exactly what you said. It seems to me it is going to be a long while before we put $150 million out again for this kind of study. It also seems to me with the time frame that is involved to test the ultimate results that we are going to have a hard time getting exactly a perfect indication of what we ought to be doing. I am a little confused as to why it took from 1965 to recently to publish the whole study anyway. That is not your responsibility. I am not asking that. It is going to be my responsibility to find out. It seems to me there is an awfully good way to plug in some warning signals even if they are not statistically reliable to where we ought to be looking and where we ought to be exploring and where we ought to be investing some money.

To duplicate something like that is obviously pretty expensive.

Dr. **Kennedy**. I might add one thing. One of the things that has really shocked me is how expensive epidemiology is. We almost have to start from scratch for each new kind of data, and you always get less than you would think you would, given the amount you have paid for it.

I do not know enough about this particular study to know why it took so long to get the data. But to somebody who comes from a different field as I do, it is just surprising how difficult it is to do these studies.

Your suggestion that we should make sure that there is not something in this large data base that we can make use of in this connection is a very good one. I think we ought to get people looking as to whether we cannot massage that computer differently to find out some things that have not been found out otherwise, and we will do it.

Senator **Schweiker**. I appreciate the comments. Whoever designed the study had some different goals and objectives in mind than what we now have. It may well be that just the way the thing was put in and coded that it would be rather difficult. But it also may be that maybe with some new look at the same data at a different way that it might be helpful.

Dr. **Kennedy**. Yes.

Senator **Javits**. When everyone is through, I have two questions.

Senator **Kennedy**. Go ahead.

Senator **Javits**. Commissioner, one thing interested me very greatly. That is emphasis upon labeling and the fact that you assume that self-interest by the patient and professional responsibility by the physician will result in labeling being effective. Is it not a fact, you also spoke of maldistribution of health care—is it not a fact that in medically underserved areas—there are unhappily for us quite a few of them in the country—in slums, in ghettos, and in rural areas, that the labeling technique alone presents a very grave difficulty because they simply are not reached by that kind of professional attention. Is that not correct?

Dr. **Kennedy**. Yes, Senator. That is certainly correct with respect to patient labeling.

I should point out that the physician labeling, of course, is intended to guide prescribing practices of physicians, and given the requirements for medical degrees in this country, we assume there is no problem in having that clearly understood in all the sectors of our health care system.

Patient labeling we have applied only to a relatively small number of classes of drugs. We are asking in the new legislation, as you know well, for expanded authority, but we recognize that patient labeling does have limitations, that there are people who cannot be reached effectively by it. We are studying ways of trying to make that labeling communicate as effectively as it can to all sorts of people in our society. But we will in no way be able to completely solve the problem. Some people will not understand it as well as they should.

It is simply a question, Senator, of having a limited number of tools to work with, and using all of them that we can.

Senator **Javits**. It also would apply to physicians in a sense that labeling helps physicians prescribe where it ought to be prescribed and to refrain from prescribing where it should not be prescribed. But if there is no physician, if the patient cannot be helped affirmatively either, the patient does not have access to that particular physician.

Dr. **Kennedy**. If the patient does not have access to the physician, the patient is not getting the drug, is not getting protection.

Senator **Javits**. The other question I had of you, sir, is this: There are few things that are clearly identifiable and as significant as birth. Indeed, my own approach to national health insurance, I am hoping that we are going to start with mothers and children—that is so sympathetic; people do not mind a capitation tax that is levied on everybody, et cetera. I would like to ask you as to this feasibility. In terms of monitoring, which is very important in this particular situation, whether it might not be possible to consider for a period of time some universal system by which the medical profession, especially the obstetrical profession, would be enlisted in a cooperative effort over a period of time, perhaps 1 year, 2, 3, to monitor births so that at one fell swoop, as it were, you could get and ingest a great amount of material which will check up on theories, hypotheses, and so on, because of the sympathetic cooperation which this invokes, to enlist a broad section of medical community dealing with births in a monitoring effort. Might not that cut through a lot of studies and so on if you have enough to base it on, and if you are computerized enough to absorb it?

I only ask you that question as a possible suggestion for looking into it because of the preciseness of incidence—it is not like some operation that may be this, that, or the other—this is it. And the monitoring which doctors may be willing to help you with, because of the sympathetic nature of the event——

Dr. **Kennedy**. I find the idea very attractive, Senator. I think among other things a major national effort to study this significant event, and then to follow it by keeping track of the children as they develop, would be one way of focusing the Nation's attention on some very important health care issues. I hope you and your colleagues on the subcommittee will be able to develop this idea further.

Senator **Javits**. You will have to give us staff assistance for us to develop an idea, if you would tell us upon rethinking what I have suggested. I am a layman, very much so, and I have no illusions about my expertise, but it is an idea that occurred to me and the staff. I would greatly appreciate it if you would think it through and give us some advice as to its feasibility and then we could perhaps give you some general authority subject to the possibility of seeking appropriation which would not require therefore a finished idea, but would require enough to justify authority with the implementation to depend on exactly how you can organize and what cooperation you give. I make that request and ask unanimous consent that whatever the Commissioner and his colleagues can come up with, we would like to have.

Dr. **Kennedy**. We will be happy to try to do that, Senator.

Senator **Kennedy**. Senator Schweiker.

Senator **Schweiker**. Commissioner Kennedy, I understand that the Ob-Gyn advisory committee only has obstetricians and gynecologists on it. If my information is correct, no neonatologists are on that committee, as I understand it, neonatologists that would specialize in the effects of medical procedures and drugs in newborn children. If my information is correct, I would like to request your consideration of putting a neonatologist on that committee in view of what is emerging from this hearing.

Dr. **Kennedy.** I think my colleagues have recognized the deficiency you allude to, Senator. I am told by Dr. Finkel we are in the process of adding one now, and obviously you are right.

Senator **Kennedy.** Just before excusing our witnesses, of course the point Senator Javits makes here is entirely appropriate. We are hopeful with this legislation that Senator Javits is cosponsoring will do the kind of technology assessment, health implications, cost implications, for hopefully all new technology that is going to come in the practice of medicine.

What we are talking about here is the classic case of ultrasound. Now, it has been approved, and it means the standard even under the medical device, in terms of safety and efficacious—well, we have it out and it is going to take continuing kind of review over a period of time in terms of real safety and efficacy. We are going to hear testimony later on this morning even with that new kind of technology that those who feel that, first of all, it is not really making any appreciable difference or any difference in terms of the treatment of both the mother and the infant. We are going to hear additional kind of testimony in terms of cost of this kind of technology so we have accepted a new type of technology without really running these things out. That is true not only in this but in all. Hopefully, what we will be able to do in a sensible and responsible way without legislation is to try and deal with these new kinds of technologies that are coming onstream, one of the important aspects of it.

Finally, Mr. Commissioner, the thing that I gather in terms of listening to your testimony is that we have rather conflicting kinds of conclusions to draw. In the one sense, a rather cautionary note, based on studies that have ben done in FDA over a period of the last 8 years about widespread use of this kind of technology. On the other hand, the current practices, at least in the view of the obstetricians and gynecologists about the use of technology, a rather important kind of disparity. When we review the use of this technology, the fact that these organizations are pressing, pushing for this technology, hospitals, more and more requiring this kind of technology, there is a disparity between the office that has the principal responsibility in terms of safety and efficacy, and those in the process of utilization of it.

That is, I am sure, a matter of some considerable concern.

I think you have appropriately warned during the course of your testimony about appropriate caution which this technology should be used.

Clearly there are examples. You have very widely pointed out, leave it up to the individual doctor in terms of dealing with this, but urging—and proliferation of this technology—and mandating by hospitals just does not make any kind of sense. You pointed this out in terms of elective induction, that it makes no sense, and your caution as well with regard to certain drugs.

Yet we are encouraged by the fact, at least your statistics indicate reduction in utilization of certain drugs during pregnancy. We hear other testimony that it really has not been reduced in any significant degree. But I suppose an important factor is not—well, it is informationally interesting that there has been some reduction—but we do not know what is appropriate use at this time of the over-the-counter drugs and these other drugs. That I think raises important areas of concern in terms of the expectant mother. We appreciate your comment. I think there are going to be a number of areas where we will have to work very closely together and work with obviously medical profession as well to try and insure that information is developed, first of all created and developed in a sound and statistical way, and that it gets out there, and it is going to be a basis for the kinds of actions within the medical profession to assure protection.

Thank you very much.

Dr. **Kennedy**. Thank you.

[The prepared statement of Dr. Kennedy follows:]

STATEMENT

BY

DONALD KENNEDY

COMMISSIONER

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

BEFORE

THE

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

COMMITTEE ON HUMAN RESOURCES

UNITED STATES SENATE

APRIL 17, 1978

Mr. Chairman:

The use of drugs and medical devices in obstetrical practice is a subject of very special concern to the Food and Drug Administration (FDA). The risks associated with their use in pregnant women involve not one but two lives: one just beginning, the other exposed to unusual physiological stress. Misuse or overuse of drugs or devices under these conditions can cause short-term harm; and--as we learned, to our sorrow in the case of diethystilbestrol (DES)--they can also produce adverse effects in the offspring that become patent long after the exposure.

I am therefore pleased to be able to discuss some of these problems, and the steps FDA is taking to help resolve them.

I want to begin this discussion with a brief survey of the important changes taking place in obstetrical care, and of the role FDA plays in assuring the safe and effective use of obstetrical drugs and devices. Then I will explore some issues that deserve special emphasis.

OBSTETRICAL CARE TODAY

The management of pregnancy and the care of obstetrical patients have improved remarkably in the last two decades.

- Disorders of pregnancy have become better understood as a result of the scientific research efforts;
- The use of drugs during pregnancy has steadily declined;

- -- Generally the nutrition, and the living conditions of pregnant women, have both improved considerably;
- -- There is increasing awareness of the necessity of early obstetrical care;
- -- New monitoring techniques have enabled physicians to make timely and important assessments of the condition of the fetus.

These improvements--accompanied by better education of physicians and patients, have markedly decreased maternal mortality and infant mortality. Twenty-five years ago, the maternal mortality rate was about 60 per 100,000 live births; today it is one-fifth of that. Neonatal mortality over this same period, has nearly halved.

Despite these significant recent gains in the quality of obstetrical care, we are nonetheless confronted by a disturbing paradox. The very techniques and products that have helped improve prenatal care and decrease infant mortality have themselves raised new questions. Useful drugs--such as anesthetics to relieve pain and oxytocins to advance labor--can, when misused or overused, result in increased risk to the patient and distress to the fetus. Beneficial techniques for monitoring fetal development--such as ultrasound--could, if misused, prove to be the agents of subtle, long-term pathological effects.

Both scientific and ethical problems attend the design and execution of studies to predict the effects of drugs and devices on the human fetus. For example, animal testing for teratogenicity, although useful, is plagued by species-to-species variation; no single animal model can be relied on as a fool-proof predictor of human fetal effects. And although dramatic adverse effects of a drug on the fetus may be discerned through careful epidemiologic search-- as with the anomalies resulting from thalidomide--adverse effects involving fetal death or subtle malformations may go undetected for some time. Minor anomalies often occur without any history of drug exposure; these represent a "background" against which drug effects are difficult to recognize. Delayed effects, even when they are striking, may escape detection until exposure is quite widespread--as with the "DES daughters."

Although epidemiology studies are thus limited, they sometimes produce extremely useful scientific data for regulatory decisionmaking. More such work is needed to help weigh the benefits and risks of a wide variety of drugs and devices. A national effort of the proper scope will require a much greater commitment of resources and effort than we have heretofore been willing to make.

These scientific problems are difficult enough; but they are made even more refractory by ethical questions involving the use of human test subjects. For example, FDA has generally excluded women of childbearing potential from the earliest phases of clinical trials, pending development of information from animal studies regarding effect on reproduction and the fetus. Although we believe that this is generally a sound policy in view of the vulnerability of the fetus to harm from drugs which cross the placental barrier, it does have the consequence of depriving women who may be pregnant from undertaking some forms of therapy. In short, our concern for the rights of subjects may collide with a broader set of patient rights. It is not easy to define a "fair" solution.

ROLE OF FDA

As you know, FDA is primarily responsible for assuring that marketed drugs and medical devices are safe, effective, and properly labeled. To help physicians and users deal with the problem of drug use in pregnancy, we have imposed labeling requirements on drugs that may be used during pregnancy: certain drugs have carried cautionary statements about the lack of information regarding fetal effects, and about the results of animal and human experiments where these were available. We shall continue to rely heavily on professional and patient labeling to minimize the use of unnecessary medication during pregnancy.

We cannot assure that drugs and devices are properly labeled, and that physicians and patients are informed of risks and benefits, without monitoring the safety and effectiveness of marketed drugs. The monitoring of drugs and devices used during pregnancy and labor cover three major categories of use: the diagnosis of pregnancy; treatment during pregnancy; and treatment during labor and delivery.

DIAGNOSTIC TESTS FOR PREGNANCY

In the past, various sex hormone preparations have been widely used for pregnancy diagnosis. They consisted of estrogen-progestin combinations, or of progestins alone, that produced withdrawal bleeding in patients who were not pregnant.

Recent reports have indicated that the use of sex hormones during early pregnancy may seriously damage the offspring. They suggest an association between hormone treatment and such congenital anomalies as heart defects and limb reduction.

FDA has concluded that the potential risk of teratogenicity argues against the use of sex hormones as a diagnostic test for pregnancy. Their use is also made unnecessary by the general availability of safer and more effective biological and immuno-chemical tests for pregnancy. Drugs used for this particular indication have been removed from the market and the labeling for all progestational drugs has been revised so that diagnostic tests for pregnancy are listed as contraindications.

DRUGS AND DEVICES USED DURING PREGNANCY

Estrogens and Progestagens

As I noted earlier, estrogens--particularly diethylstilbestrol--were widely used beginning in the 1940's for the treatment of threatened and habitual abortions. There is now considerable evidence that such drugs are ineffective for this indication; and diethylstilbestrol has been shown to be associated with a delayed risk of vaginal adenocarcinoma in female offspring. Because this study is likely to apply to all estrogenic products, the labeling is now required to list "pregnancy or suspected pregnancy" as a contraindication for the use of all such drugs.

Progestational drugs also have a history of use in the treatment of threatened and habitual abortion. The evidence we have does not show that progestagens are effective for this indication; but on the other hand, their use may be associated with an increased risk of congenital anomalies. The Agency therefore requires that progestational drug labeling carry a warning against use during the first trimester of pregnancy.

Diuretics

Thiazide diuretics have been used widely in the past in the management of edema (swelling caused by excess water retention) associated with pregnancy. The use of diuretics during pregnancy was considered at an open meeting of FDA's Obstetrics and Gynecology Advisory Committee, and as a result a series of labeling changes have been made for such drugs. These changes emphasize (1) that edema during pregnancy is very common, and usually needs no treatment other than supportive measures; (2) that diuretics do not prevent the toxemia of pregnancy, nor treat it effectively; and (3) that the routine use of diuretics exposes mother and fetus to unnecessary risk. In addition to making changes in the labeling, the Agency has also treated this subject in a Drug Bulletin article.

Drugs Used Incidentally During Pregnancy

Many pregnant women still receive drugs--both prescription and over-the-counter preparations--during the early stages of pregnancy for such minor conditions as colds, coughs, nervousness, anxiety, and other ailments for which the use of such drugs cannot be considered absolutely necessary.

Most women, I am happy to say, have a healthy skepticism about the use of drugs during early pregnancy. Media attention to the possible adverse effects on the fetus of certain drugs taken in the first trimester have increased, and most physicians have become highly selective in prescribing medication during the first trimester of pregnancy. Although this has cut down considerably on the number of drugs being used, some unnecessary use of drugs for minor conditions remains. Some of these drugs have been around for a long time, but have not been tested adequately for teratogenic effects.

We have taken several significant steps to address teratogenic risks associated with the use of drugs and alcoholic beverages.

-- Animal studies for teratogenicity are now required by the FDA before new drugs intended for use by women of childbearing potential can be marketed.

-- In newly-proposed labeling requirements for all drugs, a section on use in pregnancy will be included. The results of animal and human studies on teratogenic effects are summarized in this section to assist benefit-risk decisions. Based on such studies, certain drugs will be contraindicated for use during pregnancy, whereas others will be permitted for use at the recommended dosage. FDA's advisory panels are conducting a large scale review of safety and efficacy of OTC drugs. They have made recommendations for labeling for use by women who are or may be, pregnant.

-- FDA is developing patient information for most prescription drugs. These leaflets will provide patients, in lay language.with information about the potential risks of drugs taken during pregnancy.

-- FDA's new labeling regulations provide a cautionary note on the administration of drugs to nursing mothers; this information will also be conveyed to the patient in the patient leaflet. Most drugs taken by lactating women can be excreted in maternal milk and, therefore, ingested by the nursing infant. The long-term effects of such exposure are largely unknown.

-- The Department of Health, Education, and Welfare issued an official health caution last summer, warning that heavy use of alcohol by pregnant women may result in "Fetal Alcohol Syndrome"--a condition that includes congenital physical and mental abnormalities in the infant. The Government caution, which was drawn on the recommendation of the National Institute of Alcohol Abuse and Alcoholism, said that a risk of birth defects appears to be established with consumption above three ounces of absolute alcohol or six drinks a day. I reviewed this subject at a recent hearing before the Senate Subcommittee on Alcoholism and Drug Abuse, chaired by Senator Hathaway.

Ultrasound

An increasingly common exposure during pregnancy is to ultrasound. This technique is widely used during pregnancy to detect, visualize and monitor the fetus. Among other things, it enables the physician to determine fetal age, to detect pregnancies outside the uterus, or to diagnose fetal anomalies.

Studies of the effects of ultrasound exposure on the human fetus _in utero_ have thus far yielded inconclusive evidence. Although no increase in infant abnormalities has yet been observed, adequate studies to detect anatomical abnormalities have yet to be performed. Neither can conclusions be drawn about delayed effects.

Some scientists believe that the efficacy of ultrasound and other fetal monitoring has not been thoroughly evaluated, and benefits should therefore not be assumed. According to a recent study, the use of ultrasound to locate the placenta for amniocentesis does not appear to reduce maternal complications, and electronic monitoring of fetal heart rate--which can be done ultrasonically or by other means--appear to result in the increased use of Caesarian procedures without a resulting improvment in outcome.

To help resolve questions about the long-term effects of ultrasound, FDA is conducting a study under contract with the University of Colorado to determine whether children exposed eight to ten years ago to diagnostic ultrasound _in utero_ differ from an unexposed, otherwise similar, group of children. These children will be followed for the next three or four years to determine general health, physical and intellectual development, and neurological function. This study is largely exploratory, and should provide a basis for detailed followup and testing.

We recognize the considerable contribution that the use of ultrasound can make to diagnosis. But there is also uncertainty about the potential risks to a mother and her unborn child. There is certainly no justification for such statements as: "ultrasonography can be safely employed at any time during pregnancy" ("Current Obstetric and Gynecologic Diagnosis Treatment," 1976, p. 651). Neither can we go to the other extreme, and argue that ultrasound should be set aside until we know much more about its possible effects upon the fetus. A prudent public health policy calls for judicious use of ultrasound where the expected benefits clearly outweigh the risks.

FDA has three action programs to reduce possible risks to the public health from diagnostic ultrasound: (1) development of methods for the measurement of ultrasound intensity emitted by commerical equipment; (2) a quality assurance program to study the image quality of diagnostic equipment; (3) improved training opportunities through liaison with the professional societies; and (4) coordination with manufacturers and professional associations in the development of voluntary equipment standards.

I recently approved a proposal to develop controls over diagnostic ultrasound equipment that will guarantee the fullest possible protection to patients while taking advantage of the very important diagnostic information that can be derived from the use of ultrasound.

A symposium was held in June 1977 at FDA to examine currently supported work in ultrasound. The proceedings of the symposium have been published, and I am submitting a copy for the record.

X-Rays

Mr. Chairman, I would briefly mention another important matter: the use of X-rays during pregnancy. We have been very active recently in developing programs for reducing radiation exposure to the human embryo and the fetus. I am submitting for the record a brief summary of our recent activities in this area.

LABOR AND DELIVERY

Analgesics and Anesthetics

The relief of pain in labor present special problems. The respiratory center of the infant is highly vulnerable to sedative and anesthetic drugs, and their misuse may jeopardize neonatal respiration. This consideration is more than a mere theoretical possibility: sluggish respiration is a frequent sequel to birth in infants whose mothers have received sedation during labor.

Because no completely safe method of pain relief in obstetrics has yet been developed, it is sometimes asserted that the hazards of pain relief in labor exceed its advantages. Considerable experience, however, shows that obstetric analgesia and anesthesia, when judiciously employed, are usually beneficial rather than detrimental to the mother; adverse effects upon the infant are not usually a serious problem.

The commonly-employed analgesic drug meperidine (Demerol) has been criticized because no controlled research has established that its use is free of effects on the infant. Demerol, like other narcotic analgesics, causes mild respiratory depression in some cases. But when the drug is used judiciously, the depressing effects are usually readily reversible by modern resuscitating techniques and counteracting drugs. Long-term effects have not been adequately examined, and epidemiological studies are badly needed.

The Agency has required that Demerol labeling inform physicians that its safety in pregnancy has not been established. As an analgesic, during labor, it may have such adverse effects on the newborn as respiratory depression, and its labeling so informs the physician.

Oxytocins

Oxytocic agents (drugs which stimulate the uterus to contract) have been used for many years to advance labor and to decrease postpartum bleeding. There is a growing consensus among obstetricians that elective induction of labor (done for the convenience of the patient or physician) is undesirable because the fetus is placed at greater risk--especially where the monitoring of induction is not optimal. After careful review, FDA's Obstetric and Gynecology Advisory Committee has recommended that "elective" induction of labor should be deleted as an indication from the labeling for oxytocic drugs because the benefit-to-risk ratio cannot be defined at this time. The Committee also recommended that oxytocic drugs should be administered intravenously. Other routes of administration are presently unacceptable because they may result in uterine hypertoxicity and contribute to fetal distress. The Committee further recommended that oxytocic drugs should be administered by an automatic infusion pump or other such device for safe administration and that the patient's labor should be monitored at least with the use of an external fetal electronic monitor.

The Committee's findings and recommendations, if adopted, will have an important effect on obstetrical practice. Before taking action, FDA will hold a public hearing on June 21, 1978, so that those concerned with elective induction will have an opportunity to express their views.

SUMMARY

Mr. Chairman, much has been done by FDA, by other units of Government, and by persons outside of Government to evaluate the risks and benefits of drugs and devices and to educate physicians and users of these risks. But there remain serious problems, some inherent in the current limitations of science and others linked to resource limitations, which will not yield easy solutions. Although the benefits of some drugs and devices are readily apparent, the potential risks--especially the potential long-term teratogenic effects--are less clearly defined.

This concludes my formal statement, Mr. Chairman. If you or other members of the Subcommittee have any questions, my colleagues and I will be happy to answer them.

Senator KENNEDY. Our next panel consists of Robert Caldeyro-Barcia, M.D., president, International Federation of Gynecologists and Obstetricians, director, the World Health Organization's Latin American Center for Perinatology and Human Development, Montevideo, Uruguay; Mrs. Doris Haire, president, American Foundation for Maternal and Child Health, Inc., New York, N.Y.; Arnold D. Haverkamp, M.D., Denver General Hospital, Denver, Colo.; Ronald R. Rindfuss, Ph. D., Department of Sociology, University of North Carolina.

We will start with you, Dr. Haverkamp.

STATEMENT OF ROBERTO CALDEYRO-BARCIA, M.D., PRESIDENT, INTERNATIONAL FEDERATION OF GYNECOLOGISTS AND OBSTETRICIANS, DIRECTOR, THE WORLD HEALTH ORGANIZATION'S LATIN AMERICAN CENTER FOR PERINATOLOGY AND HUMAN DEVELOPMENT, MONTEVIDEO, URUGUAY, ACCOMPANIED BY DORIS HAIRE, PRESIDENT, AMERICAN FOUNDATION FOR MATERNAL AND CHILD HEALTH, INC., NEW YORK, N.Y.; ARNOLD D. HAVERKAMP, M.D., DENVER GENERAL HOSPITAL, DENVER, COLO.; AND RONALD R. RINDFUSS, PH. D., DEPARTMENT OF SOCIOLOGY, UNIVERSITY OF NORTH CAROLINA, A PANEL

Dr. HAVERKAMP. I am an obstetrician-gynecologist in a city-county hospital in charge of high-risk obstetrics. I have been doing research on electronic fetal monitoring for the past 4 years. I would like to share with you my experiences and the results of my studies in this limited obstetrical area. The technique of electronic fetal monitoring involves the use of a mechanical system which records both the fetal heart rate and the mother's uterine contractions on a continuous graph paper, facilitating an analysis of the health status of the fetus during a delivery.

The obstetrician is increasingly using fetal monitoring for a number of reasons:

1. The sincere desire to improve infant outcomes.
2. The desire to base his or her actions on what appear to be objective clinical data, a graph rather than a nurse's report.
3. The seeming scientific value of more information.
4. The medical/legal concern with not using a technique that a number of obstetricians state is necessary.

The obstetrical literature is replete with studies of intrapartum electronic fetal monitoring which suggest that the diagnostic technique improves perinatal outcome, reducing both mortality and morbidity of the infants [1, 2, 3, 4, 5, 6, 7, 8, 9].

Indeed, rather dramatic assumptions have been made about the potential reduction in the incidence of mental retardation if electronic monitoring were to be universally implemented. Dr. Quillian, in an editorial in "Obstetrics & Gynecology" in 1975, stated:

> * * * it seems reasonable to accept the premise that one-half of the intrapartum fetal deaths can be avoided. Likewise, assuming that brain damage is merely an intermediate point on the pathway to death, early recognition and elimination of fetal distress should reduce by one-half the incidence of handicapping disorders or mental retardation.

They further suggested that this was a cost-effective technique and that there would be significant economic advantage in electronically monitoring all labors which occur in hospitals (2, 4, 10, 11, 12).

However, we feel such enthusiastic cost-benefit analysis, unfortunately, rests on some assumptions that are not justified either in the obstetrical literature or in the literature on mental retardation. These conclusions are based on data from obstetrical studies which were either retrospective or, when prospective, did not include truly comparable study groups or the random assignment of subjects to various monitoring techniques.

Despite repeated suggestions that the differences in outcome of the infants might be somewhat subtle (5, 9) no long-term follow up of electronically monitored versus unmonitored populations have been accomplished.

Senator **Kennedy**. We have two panels. We will just go to approximately 1 o'clock. I am going to ask the remaining witnesses to be looking over their testimony to see if they can summarize it. We want to have 15 or 20 minutes for questions. We will ask you to summarize the principal points.

Dr. Haverkamp, you can go on with your testimony, and if you can summarize the central conclusions, I think that would be most useful, whichever way you want to proceed.

Dr. **Haverkamp**. It is a little difficult with the time constraints to know how long it takes. I will go ahead.

Thoughtful researchers in the field have repeatedly noted the need for a carefully controlled prospective study. As Paul and Hon have stated:

"To evaluate fetal-monitoring fully, a well-designed obstetrical study, combined with compresensive infant growth and development studies is necessary." (5)

Our studies, done in Denver, were the same studies Hon and Paul proposed at the University of Southern California in 1971, but which were not carried out. We wanted a study design in which all of the care given the pregnant patient was the same except for the technique of following fetal heart rate activity. Thus the patients would be treated at the same time, in the same institution by the same personnel. We began the study expecting improved outcome with the electronic monitoring and anticipating an ability to say just what the cost of fetal monitoring would be as well as being able to state what the perinatal gain could be with monitoring.

Maternal Child and Crippled Children's Services of HEW funded two studies, one from 1973–75 and a second from 1975 which is still ongoing. In our first study we looked at the differential effects of electronic fetal heart rate monitoring and the more routine auscultation of fetal heart tones on perinatal or infant outcomes and maternal outcomes.

Our first study population consisted of 483 high-risk pregnant patients who were admitted during labor who were to have labor induced. They were randomly assigned to one of the two groups, one in which the labor was followed by a nurse auscultating the fetal heart rate—that is, listening with a stethoscope—and a second group in which electronic fetal monitoring was employed. The study was explained to each patient and her consent was obtained before she was included in the study. The patient could withdraw from the study at any time. It was 1-to-1 care, nurse-to-patient. The outcomes in which we were interested were particularly the Apgar scores and the biochemical status of the fetus. The Apgar rating is carried out at 1 and 5 minutes after delivery and evaluates the infant's condition by considering its color, heart rate, respiration, and so forth. A good score is 10; a baby without a heartbeat has a score of zero. The condition of the infant can also be measured by the hydrogen ion concentration content of the blood from the umbilical cord. We expected that the electronically monitored infants would be in better condition than those who were merely auscultated since signs of distress could be acted on more speedily. The results of that first study revealed no improvement in Apgar scores in the electronically monitored group. Indeed, when we looked at the total number of low scores, the auscultated group seemed somewhat better off. Nor did we find differences when we compared the two study groups as to their cord hydrogen ion concentration and blood gas results.

An interesting difference was noted in the methods of delivery used in the two groups. We found 16.5 percent of the electronically monitored patients apparently required cesarean sections while only 6.6 percent of the auscultated patients were delivered in this way. This difference seemed to be the result of knowing about and taking quick action in response to a greater number of signs of fetal distress in the electronically monitored group. These results were contrary to our initial expectations. We therefore decided to pursue the matter further and commenced a second study with a tighter research design in July 1975.

This research, "Fetal Heart Rate Monitoring and Scalp Sampling in High Risk Pregnancies," is a prospective study of a carefully controlled population of 690 high-risk obstetrical patients randomly assigned to one of three types of fetal monitoring groups. Patients experienced auscultation, electronic monitoring alone, or electronic monitoring with an option to obtain fetal scalp hydrogen ion concentration. The results of this study show no statistically significant differences among the infants from the three groups with regard to immediate perinatal outcome.

All groups had excellent infant outcomes. But, again, we found that the C-section rate for the auscultated patients was 5.6 percent, while for the electronically monitored alone, 17.6 percent. This is a dramatic difference of almost three times the rate in one group. We concluded from these studies that:

First. There were no differences in neonatal outcome with respect to perinatal mortality, Apgar scores, biochemical status, nursery course, or neurological status. Among our high-risk patients, and under the circumstances of the study, electronic fetal monitoring, per se, was not associated with an improved outcome.

Second. The cesarean sectioned rate was markedly increased in electronically monitored patients—17 percent—in contrast with the auscultated group—6 percent. This was due to an increased diagnosis of both fetal distress and cephlo pelvic disproportion in the electronically monitored patients. The increase in C-sections was not associated with an improvement in perinatal outcome.

At a time when most thoughtful obstetrical authorities are urging universal electronic fetal monitoring, the study results appear unbelievable. However, if careful attention is paid to some other studies, our findings do not seem so unrealistic.

Paul found, in analyzing some 50,000 deliveries at University of Southern California from 1970–74, that there was no statistical difference in the perinatal mortality rate between monitored and unmonitored term-size infants. Neutra [14] in a retrospective study of 20,000 patients at Beth Israel Hospital in Boston, found no differences in term neonatal death rates between monitored and unmonitored patients, both being less than 1 in 1,000.

I really believe we are overselling our technology. Lilien [15] reported in 1970 from the collaborative perinatal study that term intrapartum—during labor—fetal deaths among low-risk mothers was exceedingly rare—less than 1 in 25,000 in that study. Yet many hospitals won't allow a patient to labor without a monitor and many doctors won't accept a patient who will not have a monitor because of their medical legal fears. That is an awful lot of monitoring in normal term pregnancies to gain an unclear benefit.

From our study results and in looking at the obstetrical literature, in my opinion, there is no question that fetal monitoring increases the rate of C-sections. Paul found a primary C-section rate of 16 percent for monitored and 7 percent for unmonitored at University of Southern California from 1970 to 1974 [13]. Of course, the groups are not truly comparable as the monitored patients were the high-risk patients.

I have described this study in order to illustrate some of the problems we face in deciding which costs, benefits, and risks to patients are warranted.

First. If we could extrapolate from the data of the study, we would suggest than 6 in 1,000 women were undergoing unnecessary cesarean sections.

Second. The cost of delivery rises from $700 to $3,000 while women experience the morbidity—50 percent have some form of post-operative complication—and potential mortality of major surgery.

Third. Further, they are required to undergo cesarean sections with the next pregnancies and are separated from their new infants for a significant period of time. Recent writings by pediatricians have suggested that the early contact period between mother and infant is a crucial one in that "bonding" occurs. Studies have suggested a threefold higher rate of child abuse and child deprivation in mothers undergoing cesarean sections.

Monitoring, for the mother, increases not only the cost of her delivery, but decreases the naturalness of that delivery; decreases her mobility while in labor; requires that she receive care in a rather large hospital complex thereby limiting her choice of a place in which to have her baby; and significantly increases the probability that she will have major surgery—cesarian section—during delivery.

I feel that fetal monitoring gives the doctor and nurse information. More information does not necessarily give a better outcome. It seems that in the OB patient, the more information you receive, the more anxious you become about its significance and the more aggressive to ameliorate the problem so every piece of information that looks irregular problematically is like a red flag to a conscientious physician to get in there and do something. C-sections are done by conscientious people who are nervous, not knife-happy.

Our studies certainly do not answer all the questions about monitoring. What about the very small premature infant, especially those under 3 pounds who appear to benefit from monitoring? We excluded infants under 34 weeks from the study.

In our study, each mother was attended by a registered nurse who appeared to monitor her patients at least as well as the monitor. What if the nurse was not 1 to 1, but could only intermittently check fetal rate tones of a laboring patient as so often happens on a busy labor floor? What if the same busy nurse intermittently watched a fetal monitor? If she cannot be with the patient all the time, she cannot watch the monitor continuously either. What if the nurse was not adept at auscultation of fetal heart tones? Many nurses and doctors so rely on the electronic monitors that they feel lost without them.

I believe that the technology and scientific development have enhanced our understanding of fetal stress during labor. Doctors Caldeyro-Barcia and Hon are distinguished men of science who deserve our admiration for their work. I would hope, however, that we also heed the comments of Dr. T. Almy who recently wrote an editorial in the New England Journal of Medicine [16] regarding the need for scientific trials in medicine. The reliance on clinical impression and comparison with past experience is an insufficient ethical basis for promulgating new therapies. It is because of my agreement with Dr. Almy that I wholeheartedly support S. 2466 for a National Institute of Health Care Research (Congressional Record S. 889), in which there is an expressed concern with the evaluation of technology, including "the study of the usefulness, cost, economic and social impact of medical practices and procedures."

I do have concern as to who will decide which studies are appropriate and relevant. As my own studies were turned down in 1972 by the March of Dimes and found disfavor with the people in Maternal and Infant Section of NIH because fetal monitoring was already known to be necessary and totally effective, I feel that more controlled and prospective studies are needed on fetal monitoring and I feel the need for continued support for our present studies so that the necessary follow-up as to possible later effects on the children will be done.

Finally, I fear that obstetricians may create a credibility gap and a crisis of confidence by overselling the public on high technology and aggressive obstetrics, especially when a number of people are dropping out of the system altogether and having what appear to be reasonably healthy outcomes. This would be a grave disservice to the public and medicine.

Thank you.

Senator KENNEDY. Jack, this is the only witness on this particular topic. I wonder if we might inquire of him very briefly. I only have one kind of question for you, Dr. Haverkamp.

What we heard this morning from the Commissioner of FDA was cautioning about the universal application of this fetal monitoring, the ultrasound device, and that it may have some appropriate use in certain settings, but that we did not know the long-term implications of the applications of this device.

What I understand your study—you have two studies—the conclusions of which have been reinforced by Dr. Weinberg at the School of Public Health at Harvard, which reached similar conclusions as you have done, is that it shows really no difference in the health of babies with the monitoring versus the stethoscope, but cesarean sections are up, and that with all the implications that this has in terms of cost and illness, and benefit-to-risk ratios, even utilization of such technologies is really questionable in terms of your studies with very narrow exceptions which you have identified in the latter part of your testimony and the very, very special kind of areas of very extremely high risks. Really my question is, as we have talked about in earlier panels about the risk, I suppose you are raising the serious question with regard to its effectiveness. Am I interpreting your testimony correctly, Doctor?

Dr. HAVERKAMP. That is correct. At least effectiveness of demanding this for all women in all laboring situations. As a technique that was totally efficacy proven by careful studies, that really was not done.

Senator KENNEDY. You would actually reach an extremely small percentage. At least you leave that issue open. It ought to be extremely small percentage, am I not correct, of the high risks that might be warranted?

Dr. HAVERKAMP. One of the arguments concerned is: Can a nurse follow two or three patients while in labor? These may be labor saving devices. I can say when we did it with a nurse, it was as effective as our monitoring in our hospital——

Senator KENNEDY. You did it at a hospital with cheaper cost and fewer cesareans, is that correct?

Dr. HAVERKAMP. Unquestionably less cesarean sections.

Senator KENNEDY. A lot less expensive in terms of cost——

Dr. HAVERKAMP. Cesarean sections are costly. Nurses are costly, too.

Senator SCHWEIKER. Why, Dr. Haverkamp, in your judgment is there more propensity to have cesarean section if you have monitoring technique used? I am not clear as to why you say that happens.

Dr. HAVERKAMP. I think in my estimation that is true. Every study you take a look at where there is monitoring technique used finds higher rate.

The tendency is to assure you have a good outcome for fetus at the expense of mother having cesarean section. I really feel that perhaps in that we are being overly aggressive to the detriment of the mother.

Senator SCHWEIKER. Does the physician under those circumstances perceive there is something wrong with the fetus that makes them decide to do a Caesarean section?

Dr. HAVERKAMP. You get a lot more information from electronic monitor. If you then react on that information and the problem is to distinguish what is stress that is tolerable for an infant from stress which is dangerous—so the doctor, it appears to me, reacts with more information without an end point seeing necessarily any beneficial result.

Senator SCHWEIKER. The doctor gets more information, and then makes a judgment that a caesarean section is needed. Your data indicate that the outcome would have been the same in terms of the baby's overall health, whether the cesarean section was done or not?

Dr. HAVERKAMP. That is right. With auscultation, without information, there is no way a nurse can, by auscultation—you can with electronic monitoring—it did not ultimately make a significant difference.

Senator SCHWEIKER. Nobody's life was saved and no baby's health was improved by using ceasarean section techniques coupled with monitoring techniques versus other techniques, is that what you are saying?

Dr. HAVERKAMP. There is no difference. That is correct.

Senator JAVITS. I just have one question.

I picked up in your testimony something that interested me greatly. That is, the one statement you have on page 3, last paragraph from the bottom, next to last sentence:

> Yet, many hospitals won't allow a patient to labor without a monitor and many doctors won't accept a patient who will not have a monitor because of their medical legal fears.

Percentages of monitoring, of course, are borne out by this study by the staff. Many hospitals are 100 percent. To what extent do you find that that is connected with this whole scare about malpractice suits?

Dr. HAVERKAMP. I think it definitely is. The doctor is in a dilemma to not have a technique that appears available and not use it. It is vulnerable to criticism, and I think that adds tremendous impetus to them using technology even as I state that it is not totally proven. That is the problem.

We made the jump to accept completely the technology and its efficacy without doing the proper studies, so you could concretely say how effective it was.

Senator JAVITS. Then you believe the practice has direct connection with the dangers and high cost of malpractice insurance, and the results of malpractice litigation?

Dr. HAVERKAMP. There is no question that the physician today reacts more aggressively in obstetrics because of the fear of malpractice.

Senator JAVITS. Do you have any ideas as to what we can do about it?

Dr. HAVERKAMP. No. I believe, again, before we accept technologies that may not be effective, and say a physician must use them, we must know the true effectiveness of them. We have to be in a position to make rational decisions.

Senator JAVITS. There is nothing that says the physician must use this, except his own concern about his malpractice insurance, which might be canceled on him, or his own concern about findings of a jury in a malpractice case, is that not true?

Dr. HAVERKAMP. There are a number of obstetricians who have stated that monitoring is necessary, and a number of leading obstetrical figures that say it is malpractice not to use monitors.

Senator JAVITS. On a professional basis?

Dr. HAVERKAMP. On a professional basis. There have been lawyers from the University of Southern California who have given an opinion if you did not use a monitor, you would be medically, legally liable.

Senator JAVITS. You do not agree with that?

Dr. HAVERKAMP. I do not agree with that.

Senator JAVITS. Your findings indicate that you have a right not to agree with it?

Dr. HAVERKAMP. That is right.

Senator JAVITS. There is a scientific basis, and data base for your view?

Dr. HAVERKAMP. Yes.

Senator JAVITS. Thank you very much.

[The prepared statement of Dr. Haverkamp follows:]

Comments of Dr. Albert D. Haverkamp before the Senate Sub-Committee on Health, April 17, 1978

I am an obstetrician-gynecologist in a city-county hospital in charge of high-risk obstetrics. I have been doing research on electronic fetal monitoring for the past four years. I would like to share with you my experiences and the results of my studies in this limited obstetrical area. The technique of electronic fetal monitoring involves the use of a mechanical system which records both the fetal heart rate and the mother's uterine contractions on a continuous graph paper, facilitating an analysis of the health status of the fetus during a delivery.

The obstetrician is increasingly using fetal monitoring for a number of reasons: 1) the sincere desire to improve infant outcomes; 2) the desire to base his or her actions on what appear to be objective clinical data, a graph rather than a nurse's report; 3) the seeming scientific value of more information; 4) the medical legal concern with not using a technique that a number of obstetricians state is necessary.

The obstetrical literature is replete with studies of intrapartum electronic fetal monitoring which suggest that this diagnostic technique improves perinatal outcome, reducing both mortality and morbidity of the infants (1, 2, 3, 4, 5, 6, 7, 8, 9).

Indeed, rather dramatic assumptions have been made about the potential reduction in the incidence of mental retardation if electronic monitoring were to be universally implemented. Quilligan, in an editorial in Obstetrics & Gynecology in 1975, stated...."it seems reasonable to accept the premise that one-half of the intrapartum fetal deaths can be avoided. Likewise, assuming that brain damage is merely an intermediate point on the pathway to death, early recognition and elimination of fetal distress should reduce by one-half the incidence of handicapping disorders or mental retardation" (9). They further suggested that this was a cost-effective technique and that there would be significant economic advantage in electronically monitoring all labors which occur in hospitals (2, 10, 4, 11, 12).

Such enthusiastic cost-benefit analysis, unfortunately, rests on some assumptions that are not justified either in the obstetrical literature or in the literature on mental retardation. These conclusions are based on data from obstetrical studies which were either retrospective or, when prospective, did not include truly comparable study groups nor the random assignment of subjects to various monitoring techniques.

Despite repeated suggestions that the differences in outcome of the infants might be somewhat subtle (5, 9) no long-term follow-up of electronically monitored versus unmonitored populations has been accomplished. Thoughtful researchers in the field have repeatedly noted the need for a carefully controlled prospective study. As Paul and Hon have stated: "To evaluate fetal monitoring fully, a well-designed obstetrical study, combined with comprehensive infant growth and development studies in necessary". (5)

Our studies, done in Denver, were the same studies Hon and Paul proposed at the University of Southern California in 1971, but which were not carried out. We wanted a study design in which all of the care given the pregnant patient was the same except for the technique of following fetal heart rate activity. Thus the patients would be treated at the same time, in the same institution by the same personnel. We began the study expecting improved outcome with the electronic monitoring and anticipating an ability to say just what the cost of fetal monitoring would be as well as being able to state what the perinatal gain could be with monitoring.

Maternal Child and Crippled Children's Services of HEW funded two studies, one from 1973-1975 and a second from 1975 which is still ongoing. In our first study we looked at the differential effects of electronic fetal heart rate monitoring and the more routine auscultation of fetal heart tones on perinatal or infant outcomes and maternal outcomes.

Our first study population consisted of 483 high-risk pregnant patients who were admitted during labor or who were to have labor induced. They were randomly assigned to one of the two groups, one in which the labor was followed by a nurse auscultating the fetal heart rate (i.e. listening with a stethoscope), and a second group in which electronic fetal monitoring was employed. The study was explained to each patient and her consent was obtained before she was included in the study. The patient could withdraw from the study at any time. It was one-to-one care, nurse-to-patient, or nurse-machine-to-patient. The outcomes in which we were interested were particularly the Apgar scores and the biochemical status of the fetus. The Apgar rating is carried out at one and five minutes after delivery and evaluates the infant's condition by considering its color, heart rate, respiration, etc. A good score is 10; a baby without a heart beat has a score of zero. The condition of the infant can also be measured by the pH content of the blood from the umbilical cord. We expected that the electronically monitored infants would be in better condition than those who were merely auscultated since signs of distress could be acted upon more speedily. The results of that first study revealed no improvement in Apgar Scores in the electronically monitored group. Indeed, when we looked at the total number of low scores the auscultated group seemed somewhat better off. Nor did we find differences when we compared the two study groups as to their cord pH and blood gas results.

An interesting difference was noted in the methods of delivery used in the two groups. We found 16.5 percent of the electornically monitored patients apparently required Caesarean sections while only 6.6 percent of the auscultated patients were delivered in this way. This difference seemed to be the result of knowing about and taking quick action in response to a greater number of signs of fetal distress in the electronically monitored group. These results were contrary to our initial expectations. We therefore decided to pursue the matter further and commenced a second study with a tighter research design in July, 1975.

This research, "Fetal Heart Rate Monitoring and Scalp Sampling in High Risk Pregnancies" is a prospective study of a carefully controlled population of 690 high-risk obstetrical patients randomly assigned to one of three types of fetal monitoring groups. Patients experienced auscultation, electronic monitoring alone, or electronic monitoring with an option to obtain fetal scalp pH. The results of this study show no statistically significant differences among the infants from the three groups with regard to immediate perinatal outcome.

All groups had excellent infant outcomes. But, again, we found that the C-section rate for the auscultated patients was (5.6%) while for the electronically monitored alone (17.6%). This is a dramatic difference of almost 3 times the rate in one group. We concluded from these studies that:

1) There were no differences in neonatal outcome with respect to perinatal mortality, Apgar Scores, biochemical status, nursery course, or neurological status. Among our high risk patients, and under the circumstances of the study, electronic fetal monitoring, per se, was not associated with an improved outcome;

2) The Caesarean sectioned rate was markedly increased in electronically monitored patients (17%) in contrast with the auscultated group (6%). This was due to an increased diagnosis of both fetal distress and cephlo pelvic disproportion in the electronically monitored patients. The increase in C-sections was not associated with an improvement in perinatal outcome.

At a time when most thoughtful obstetrical authorities are urging universal electronic fetal monitoring, the study results appear unbelievable. However, if careful attention is paid to some other studies our findings do not seem so unrealistic.

Paul (13) found in analyzing some 50,000 deliveries at USC from 1970-1974 that there was no statistical difference in the perinatal mortality rate between monitored and unmonitored term size infants. Neutra (14) in a retrospective study of 20,000 patients at Beth Israel Hospital in Boston found no differences in term neonatal death rates between monitored and unmonitored patients (both being less than 1/1000).

I really believe we are over-selling our technology. Lilien (15) reported in 1970 from the Collaborative Perinatal study that term intrapartum (during labor) fetal deaths among low-risk mothers was exceedingly rare--less than 1/25,000 in that study. Yet, many hospitals won't allow a patient to labor without a monitor and many doctors won't accept a patient who will not have a monitor because of their medical legal fears. That is an awful lot of monitoring in normal term pregnancies to gain an unclear benefit.

From our study results and in looking at the obstetrical literature, in my opinion, there is no question that fetal monitoring increases the rate of C-sections. Paul found a primary C-section rate of 16% for monitored and 7% for unmonitored at USC from 1970-1974 (13). Of course, the groups are not truly comparable as the monitored patients were the high risk patients.

I have described this study in order to illustrate some of the problems we face in deciding which costs, benefits and risks to patients are warranted.

1) If we could extrapolate from the data of our study, we would suggest that 6/100 women were undergoing unnecessary Caesarean sections.

2) The cost of delivery rises from $700 to $3,000 while women experience the morbidity (50% have some form of post-operative complication) and potential mortality of major surgery.

3) Further, they are required to undergo Caesarean sections with the next pregnancies and are separated from their new infants for a significant period of time. Recent writings by pediatricians have suggested that the early contact period between mother and infant is a crucial one in that "bonding" occurs. Studies have suggested a three-fold higher rate of child abuse and child deprivation in mothers undergoing Caesarean sections.

Monitoring, for the mother, increases not only the cost of her delivery, but decreases the naturalness of that delivery; decreases her mobility while in labor; requires that she receive care in a rather large hospital complex thereby limiting her choice of a place in which to have her baby; and significantly increases the probability that she will have major surgery (Caesarian section) during delivery.

I feel that fetal monitoring gives the doctor and nurse information. More information doesn't necessarily give a better outcome. It seems that in the OB patient, the more information you receive the more anxious you become about its significance and the more aggressive to ameliorate the problem so every piece of information that looks irregular problematically is like a red flag to a conscientious physician to get in there and do something. C-sections are done by conscientious people who are nervous, not knife-happy.

Our studies certainly do not answer all the questions about monitoring. What about the very small premature infant, especially those under 3 lbs who appear to benefit from monitoring? We excluded infants under 34 weeks from the study.

In our study, each mother was attended by a registered nurse who appeared to monitor her patients at least as well as the monitor. What if the nurse was not one-to-one, but could only intermittently check fetal rate tones of a laboring patient as so often happens on a busy labor floor? What if the same busy nurse intermittently watched a fetal monitor? If she cannot be with the patient all the time, she cannot watch the monitor continuously either. What if the nurse was not adept at auscultation of fetal heart tones? Many nurses and doctors so rely on the electronic monitors that they feel lost without them.

I believe that the technology and scientific development have enhanced our understanding of fetal stress during labor. Doctors Caldeyro-Barcia and Hon are distinguished men of science who deserve our admiration for their work. I would hope, however, that we also heed the comments of Dr. T. Almy who recently wrote an editorial in the New England Journal of Medicine (16) regarding the need for scientific trials in medicine. The reliance on clinical impression and comparison with past experience is an insufficient ethical basis for promulgating new therapies. It is because of my agreement with Dr. Almy that I wholeheartedly support Senate Bill 2466 for a National Institute of Health Care Research (Congressional Record S889), in which there is an expressed concern with the evaluation of technology, including "the study of the usefulness, cost, economic and social impact of medical practices and procedures."

I do have concern as to who will decide which studies are appropriate and relevant. As my own studies were turned down in 1972 by the March of Dimes and found disfavor with the people in Maternal and Infant Section of N.I.H. because fetal monitoring was already known to be necessary and totally effective, I feel that more controlled prospective studies are needed on fetal monitoring and I feel the need for continued support for our present studies so that the necessary follow-up as to possible later effects on the children will be done.

Finally, I fear that obstetricians may create a credibility gap and a crises of confidence by overselling the public on high technology and aggressive obstetrics, especially when a number of people are dropping out of the system altogether and having what appear to be reasonably healthy outcomes. This would be a grave disservice to the public and medicine.

BIBLIOGRAPHY

1. Anonymous. "Is fetal monitoring worthwhile." *Brit Med J 1:* 515, 1971

2. Beard RW, Filshie GM, Knight CA, Roberts GM. "Intensive care of high risk fetus in labour." *J Obstet Gynaecol Brit Commonw 78*:865, 1971.

3. Gabert HA, Stenchever MA "Continuous electronic monitoring of fetal heart rate during labor." *Am J Obstet Gynecol 115*: 919, 1973

4. Keily VC, Kulkarni D: "Experiences with fetal monitoring in a community hospital." *Obstet Gynecol 4*: 816, 1973

5. Paul RH, Hone EH. "A Clinical fetal monitoring." *Am J Obstet Gynecol 113*: 529, 1974.

6. Paul RH: Clinical fetal monitoring. Experience on a large clinical fetal monitoring. Experience on a large clinical serviec. *Am J Obstet Gynecol 113*: 573, 1972.

7. Amato, JC, "Fetal Monitoring in a Community Hospital." *Obstet & Gynecol 50:* 269, 1977.

8. Renou P, Chang A, Anderson I, Wood C, "Controlled trial of fetal intensive care." *Am J Obstet Gynecol 126*: 470, 1976.

9. Quilligan E, Paul R, "Fetal Monitoring; Is It Worth It?" *Obstet & Gynecol 44:* 96, 1975.

10. Bowe ET, in *Fetal Growth and Development*, Harry A Waisman and George Kerr, editors, New York City, McGraw-Hill Book Co., 1970

11. Saling, EZ, Dudenhausen JW. "The present situation of clinical monitoring of the fetus during labor." *J of Perinatal Medicine* 73: 144, 1973.

12. Shenker L: "Clinical experience with fetal heart rate monitoring on one thousand patients in labor." *Am J Obstet Gynecol 115*: 1111, 1973.

13. Paul RH, Huey JR, Yaeger CF,"Clinical fetal monitoring." *Postgraduate Medicine 61:* 160, 1977.

14. Neutra R, Fienberg SE, Friedman E, "The Impact of Fetal Monitoring on Neonatal Death." APHA Meeting, Washington, D.C. Oct. 1977.

15. Lilien AA, "Team Intapartum Fetal Death." *Am J Obstet Gynecol 107*: 595, 1970.

16. Almy, T. Editorial "Therepeutic Trials, Town and Gown, and The Public Interest," *New England Journal of Medicine*. 296: 280, 1977.

Senator **Kennedy**. Doctor Rindfuss.

Dr. **Rindfuss**. I have a cold today. If you cannot hear me, just let me know.

Today I will make two main points. First, our research has shown that elective induction of labor is a common obstetric practice throughout the United States.

Second, our research and the research of others indicates that elective induction of labor introduces risks to the health and life of mothers and children. Given these two findings, the question that must be faced by prospective parents, physicians and those in a position to legislate policy is: Should we tolerate even very small increases in risk to the mother or the child simply for the sake of convenience?

By "elective induction of labor" I mean the practice of starting labor for nonmedical reasons prior to its spontaneous occurrence by the use of drugs, mechanical means, or both. Labor may also be induced for medical reasons such as preeclampsia, diabetes, or RH disease. This would be a "medically indicated induction."

For elective inductions, the justification exists at the personal and scheduling preference level, rather than at the medical level. The practice has appeal because it introduces predictability. One of its early proponents put it this way: "it is high time we shed our shame over preferring to practice obstetrics in the daytime" ((R. E. Hall, Bull., Sloane Hospital, Women 7:55, 1960).

Our work shows elective induction is widely practiced. However, because State or National data do not tabulate the incidence of elective inductions, our evidence is indirect. In fact, there are no data available that would tell us how many inductions occur. Our indirect evidence is obtained from birth registration data—specifically the day of the week on which births occur.

Our initial work was confined to the State of Wisconsin (R. R. Rindfuss and J. L. Ladinsky, Medical Care, 8:685, 1976). [This paper is attached as an appendix to the present statement.] We found that there were about 15 percent fewer deliveries on Sundays, and 6 percent fewer births on Saturdays than one would expect if births followed a simple random pattern. The greatest number of births occurred on Tuesdays and Wednesdays. The weekend birth deficit is found week after week, month after month. The only exceptions occur around holidays. In the weeks containing the Fourth of July, Labor Day, Thanksgiving, and Christmas, the holiday has fewer births than the associated Sunday.

It might be argued that this weekend deficit of births is the result of scheduled cesarean sections. However, when cesarean deliveries are eliminated, the weekend deficit persists.

Obstetrical tests suggest that induction of labor be considered when a woman lives a substantial distance from the hospital—particularly in the case of a multipara woman with a history of rapid labors. This is a medical reason for induction. It should lead to a larger weekend deficit in rural areas. We found the reverse: the weekend deficit is greater in urban areas.

In more recent work we examined data for the entire United States and Canada, and found a similar pattern nationwide. This more recent work is currently under review for publication in a scientific journal.

We have expected the weekend deficit to be more pronounced among women receiving prenatal care. The reason is that, when the patient has been seen by an obstetrician since early in her pregnancy, then the obstetrician is in a better position to evaluate whether she is at term. For those who began prenatal care in the first or second month of pregnancy, the weekend deficit is largest. The size of the deficit diminishes steadily as patients begin their prenatal care later and later in their pregnancy. For those who receive no prenatal care, there is essentially no weekend deficit.

For Canada, we were able to examine the trend in this weekend deficit from 1951 to 1971. The drug usually used in elective inductions was not synthesized until the midfifties. If the weekend deficit is caused by inductions, then there should be an increasing trend from 1951 to 1971. And, indeed, there is such a trend. In 1951, the pattern of births by day of the week was almost random. Today there are large differences between weekends and weekdays.

Unfortunately, this indirect evidence does not indicate the full magnitude of the use of elective inductions. The reason is that some patients and/or physicians prefer to schedule delieveries on weekends. We have been able to demonstrate this by examining the maternity room log from one Midwestern hospital for all of 1975.

When we have discussed our findings with practicing obstetricians, they have not argued with our inferences. In fact, quite the opposite has happened. They inform us that everyone knows that elective induction of labor is a common practice. They wonder why we choose to point it out.

When we discuss our findings with nonmedical persons, we get a very different reaction. They cannot imagine the practice is as common as we show it is.

If elective induction were an accepted medical practice without risk, then the fact that it is a common practice would be of little interest. However, elective induction is neither an accepted practice, nor is it free of risk.

Obstetrical textbooks almost unanimously discourage the use of elective inductions. For example, Page Villee and Villee state that:

> Elective inductions purely for convenience are generally frowned upon, because in large series, about one fetal death in 200 inductions have been directly attributable to the procedure—(Human Reproduction: The Care Content of Obstetrics, Gynecology and Perinatal Medicine, W. G. Saunders Co., 1976, p. 308).

As the above quote implies, the safety of elective induction has never been conclusively established. Studies examining the benefits and risks of elective induction have arrived at conflicting results. I feel that the reason for the conflicting results is that the negative consequence of elective induction occur only rarely; and rare effects are not consistently visible when only a few subjects are used—as is the case in most clinical studies.

This was noted earlier by Commissioner Kennedy.

For example, if severe neurological damage occurred only once in every 10,000 cases, the possibility of detecting this risk with clinical trials would be small.

We examined the risks associated with elective induction of labor by using records of 140,000 live births that occurred in New York City in 1968. I will not discuss all the details of our study today. The complete study will be published this fall in the American Journal of Public Health, and interested persons should consult the full report.

However, I can report that our results suggest that in 1968 in New York City, the elective induction of labor introduced risk to the fetus, and in some hospital care settings this risk was substantial. Other studies, such as those by Niswander, Liston, Caleyro-Barcia, Dunn and Jewett, have also found a variety of hazards associated with elective induction.

Some obstetricians maintain that our findings from 1968 New York City data do not apply to today's obstetrical practice. They argue that, because of the new technologies developed since 1968, induction has become safer. This may or may not be true. The technologies now being used may have adverse effects of their own.

For example, one way to see if the fetus is at term is to use amniocentesis. This procedure reduces the possibilitiy of inducing a premature fetus. Yet, amniocentesis has risks attached to it—rare, but nevertheless real. Another example is the use of ultrasound. It has been established that ultrasound does not have the complications that X-rays do; but other effects of ultrasound are still being examined. We do not yet have conclusive evidence that there are no complications associated with ultrasound.

In short, we do not know whether the new technologies have made elective inductions safer or riskier. And more to the point, we do not know if these new technologies are used in every elective induction. These are researchable questions, but we do not currently have the answers.

In my opinion, at present the safety of elective inductions has not been conclusively established at this time. In fact, a number of studies suggest the opposite.

When labor is induced for convenience, whose convenience is being served, the baby's, the mother's, the physician's? By definition the baby is not being consulted or served. It is unknown at present whether inductions are done more for the convenience of mothers-to-be or the doctors and hospitals that deliver them. This is a major unanswered question, and further resarch is needed on this issue.

One can imagine a variety of reasons why a mother—and a father—might prefer to have a scheduled delivery. Plans can be made for the care of other children. The woman can be assured that her obstetrician will deliver her baby. The woman can be assured that adequate back-up personnel will be available—which is not always the case on weekends or nights. The anxiety of waiting for labor to begin is removed, and this may put the mother in a better psychological frame of mind.

If it is primarily the patient's convenience that is being served, then the patient must make the final decision about whether to have an elective induction. If the patient is to make the final decision, then sufficient information must be available to the patient to make a reasoned decision.

We cannot expect mothers to read medical journals. Some way to provide information to prospective parents is needed. Then the mother can decide if any chance that her baby will be damaged as a result of elective induction is worth the convenience.

It is also easy to think of a variety of reasons why physicians would prefer to have scheduled deliveries. One obstetrician told me that he induced 40 percent of his patients. When asked why, he said that he preferred to have weekends with his family—something we can all understand. Another obstetrician told me that he preferred scheduled deliveries because they did not interfere with his office schedule. Another reported that with an induced labor, he was able to devote full attention to his patient. Another said that the nurses were best during the Monday to Friday day shift.

It is also easy to understand why obstetricians would want predictability in their lives. What I cannot understand is why a person desiring a predictable daily and weekly schedule would become an obstetrician. This is a question that needs to be faced by medical students. What the public has to ask and answer is first, whether any medical procedure that might introduce an increased risk to patients, no matter how small that risk is, can be tolerated on the grounds that it is convenient for the physician; and second, if yes, then what level of risk is acceptable?

When considering elective induction of labor, it is important to remember that virtually all medical procedures entail some risk to the patient. This is a fact of life that physicians must live with. The usual clinical justification for introducing risk to the patient is to remedy some actual or potential health problem.

In general, risk is introduced when the medical benefit is perceived to be greater than the potential risk. In such a situation, minor side effects and side effects that occur very rarely are not sufficient grounds for deciding against the procedure. This is as it should be.

Elective induction of labor, however, involves fundamentally different considerations. By definition, elective induction of labor has no explicit or implicit medical beenfit. Rather, the benefit is measured in terms of convenience, either to the patient or the physician. In this situation, side effects that are minor or rare cannot be dismissed. Until it can be shown, beyond any reasonable doubt, that there are absolutely no negative side effects produced as a result of elective induction of labor, the procedure should not be used in routine obstetrical care.

To summarize, elective induction of labor appears to be a common obstetrical practice, and it appears to introduce risk to the baby and to the mother. Given the current situation, I think there are two courses of action that this subcommittee might pursue:

1. Promote research on the unanswered questions in this area, and
2. Maximize the dissemination of currently available information so that informed decisions can be made by parents. With respect to the first, it is clear that there are a large number of unanswered questions.

For example, we do not know the full magnitude of the incidence of elective induction. I recommend that this subcommittee see that adequate money and resources are available to allow researchers to adequately monitor the incidence and safety of elective induction techniques. This must include surveillance of rare, but serious, side effects.

Thank you.

[The prepared statement of Dr. Rindfuss follows:]

THE IMPLICATIONS OF THE ELECTIVE INDUCTION OF LABOR FOR THE HEALTH OF MOTHERS AND CHILDREN

Statement prepared for the United States Senate
Subcommittee on Health and Scientific Research

Ronald R. Rindfuss
Department of Sociology
University of North Carolina
Chapel Hill, North Carolina 27514

April 17, 1978

In this statement I make two main points. First, our research has shown that elective induction of labor is a common obstetric practice throughout the United States. Second, our research and the research of others indicates that elective induction of labor introduces risks to the health and life of mothers and children. Given these two findings, the question that must be faced by prospective parents, physicians, and those in a position to legislate policy is: Should we tolerate even very small increases in risk to the mother or the child simply for the sake of convenience?

By "elective induction of labor" I mean the practice of starting labor for nonmedical reasons prior to its spontaneous occurrence by the use of drugs, mechanical means, or both. Labor may also be induced for medical reasons such as preeclampsia, diabetes, or RH disease; this would be a "medically-indicated induction." For elective inductions, the justification exists at the personal and scheduling-preference level, rather than at the medical level. The practice has appeal because it introduces predictability. One of its early proponents put it this way: "It is high time we shed our shame over preferring to practice obstetrics in the daytime" (R. E. Hall, Bull. Sloane Hosp. Women 7:55, 1961).

A. Incidence of Elective Induction

Our work shows elective induction is widely practiced.

However, because state or national data do not tabulate the incidence of elective inductions,* our evidence is indirect. In fact, there are no data available that would tell us how many inductions occur. Our indirect evidence is obtained from birth registration data--specifically the day of the week on which births occur.

Our initial work was confined to the state of Wisconsin (R. R. Rindfuss and J. L. Ladinsky, Medical Care 8:685, 1976). [This paper is attached as an appendix to the present statement.] We found that there were about 15 percent fewer deliveries on Sundays and 6 percent fewer births on Saturdays than one would expect if births followed a simple random pattern. The greatest numbers of births occurred on Tuesdays and Wednesdays. The weekend birth deficit is found week after week, month after month. The only exceptions occur around holidays. In the weeks containing the Fourth of July, Labor Day, Thanksgiving, and Christmas, the holiday has fewer births than the associated Sunday.

It might be argued that this weekend deficit of births is the result of scheduled Caesarean sections. However, when Caesarean deliveries are eliminated, the weekend deficit persists.

Obstetrical texts suggest that induction of labor be considered when a woman lives a substantial distance from the hospital--particularly in the case of a multipara woman with a history of rapid labors. This is a medical reason for induction. It should lead to a larger weekend deficit in rural areas. We found the reverse: the weekend deficit is greater in urban areas.

---

*New York City is the only exception. It routinely records whether or not deliveries are electively induced.

In more recent work we examined data for the entire United States and for Canada, and found a similar pattern nationwide. [This more recent work is currently under review for publication in a scientific journal.]

We had expected the weekend deficit to be more pronounced among women receiving early prenatal care. The reason is that, when the patient has been seen by an obstetrician since early in her pregnancy, then the obstetrician is in a better position to evaluate whether she is at term. For those who began prenatal care in the first or second month of pregnancy, the weekend deficit is largest. The size of the deficit diminishes steadily as patients begin their prenatal care later and later in their pregnancy. For those who receive no prenatal care, there is essentially no weekend deficit.

For Canada, we were able to examine the trend in this weekend deficit from 1951 to 1971. The drug usually used in elective inductions was not synthesized until the mid-1950s. If the weekend deficit is caused by inductions, then there should be an increasing trend from 1951 to 1971. And, indeed, there is such a trend. In 1951, the pattern of births by day of the week was almost random. Today there are large differences between weekends and weekdays.

Unfortunately, this indirect evidence does not indicate the full magnitude of the use of elective inductions. The reason is that some patients and/or physicians prefer to schedule deliveries on weekends. We have been able to demonstrate this by examining the maternity room log from one midwestern hospital for all of 1975.

When we have discussed our findings with practicing obstetricians, they have not argued with our inferences. In fact, quite the opposite has happened. They inform us that everyone knows that elective induction of labor is a common practice. They wonder why we choose to point it out. When we discuss our findings with non-medical persons, we get a very different reaction. They cannot imagine the practice is as common as we show it is.

B. Risks Associated with Elective Induction

If elective induction were an accepted medical practice without risk, then the fact that it is a common practice would be of little interest. However, elective induction is neither an accepted medical practice, nor is it free of risk.

Obstetrical textbooks almost unanimously discourage the use of elective inductions. For example, Page, Villee and Villee state that: "Elective inductions purely for convenience are generally frowned upon, because in large series, about one fetal death in 200 inductions has been directly attributable to the procedure" (Human Reproduction: The Care Content of Obstetrics, Gynecology and Perinatal Medicine, W. G. Saunders Co., 1976, p. 308).

As the above quote implies, the safety of elective induction has never been conclusively established. Studies examining the benefits and risks of elective induction have arrived at conflicting results. I feel that the reason for the conflicting results is that the negative consequences of elective induction occur only rarely; and rare effects are not consistently visible when only a few subjects are used--as is the case in most clinical studies. For example, if severe neurological damage occurred only once in every 10,000 cases, the possibility of detecting this risk with clinical trials would be small.

We examined the risks associated with elective induction of labor by using records of 140,000 live births that occurred in New York City in 1968. I can not discuss all the details of our study today. The complete study will be published this fall (in the American Journal of Public Health), and interested persons should consult the full report. However, I can report that our results suggest that in 1968 in New York City, the elective induction of labor introduced risk to the fetus, and in some hospital care settings this risk was substantial. Other studies, such as those by Niswander, Liston, Caleyro-Barcia, Dunn and Jewett, have also found a variety of hazards associated with elective induction.

A number of obstetricians maintain that our findings from 1968 New York City data do not apply to today's obstetrical practice. They argue that, because of the new technologies developed since 1968, induction has become safer. This may or may not be true. The technologies now being used may have adverse effects of their own. For example, one way to see if the fetus is at term is to use amniocentesis. This procedure reduces the possibility of inducing a premature fetus. Yet, amniocentesis has risks attached to it--rare but nevertheless real. Another example is the use of ultra sound. It has been established that ultra sound does not have the complications that x-rays do; but other effects of ultra sound are still being examined. We do not yet have conclusive evidence that there are no complications associated with ultra sound.

In short, we do not know whether the new technologies have made elective inductions safer or riskier. And more to the point, we do not know if these new technologies are used in every elective induction. These are researchable questions, but we do not currently have the answers. In my opinion, at present the safety of elective inductions has not been conclusively established at this time. In fact, a number of studies suggest the opposite.

C. Whose Convenience and Is It Justifiable?

When labor is induced for convenience, whose convenience is being served: the baby's, the mother's, the physician's? By definition the baby is not being consulted or served. It is unknown at present whether inductions are done more for the convenience of mothers-to-be or the doctors and hospitals that deliver them. This is a major unanswered question, and further research is needed on this issue.

One can imagine a variety of reasons why a mother (and a father) might prefer to have a scheduled delivery. Plans can be made for the care of other children. The woman can be assured that her obstetrician will deliver her baby. The woman can be assured that adequate back-up personnel will be available--which is not always the case on weekends or nights. The anxiety of waiting for labor to begin is removed, and this may put the mother in a better psychological frame of mind.

If it is primarily the patient's convenience that is being served, then the patient must make the final decision about whether to have an elective induction. If the patient is to make the final decision, then sufficient information must be available to the patient to make a reasoned decision. We cannot expect mothers to read medical journals. Some way to provide information to prospective parents is needed. Then the mother can decide if any chance that her baby will be damaged as a result of elective induction is worth the convenience.

It is also easy to think of a variety of reasons why physicians would prefer to have scheduled deliveries. One obstetrician told me that he induced 40 percent of his patients. When asked why, he said that he preferred to have weekends with his family--something we can all understand. Another obstetrician told me that he preferred scheduled deliveries because they did not interfere with his office schedule. Another reported that with an induced labor, he was able to devote full attention to his patient. Another said that the nurses were best during the Monday to Friday day shift.

It is easy to understand why obstetricians would want predictability in their lives. What I can not understand is why a person desiring a predictable daily and weekly schedule would become an obstetrician. This is a question that needs to be faced by medical students. What the public has to ask and answer is first, whether any medical procedure that might introduce an increased risk to patients, no matter how small that risk is, can be tolerated on the grounds that it is convenient for the physician; and second, if yes, then what level of risk is acceptable.

When considering elective induction of labor, it is important to remember that virtually all medical procedures entail some risk to the patient. This is a fact of life that physicians must live with. The usual clinical justification for introducing risk to the patient is to remedy some actual or potential health problem. In general, risk is introduced when the medical benefit is perceived to be greater than the potential risk. In such a situation, minor side effects and side effects that occur very rarely are not sufficient grounds for deciding against the procedure. This is as it should be.

Elective induction of labor, however, involves fundamentally different considerations. By definition, elective induction of labor has no explicit or implicit medical benefit.

Rather, the benefit is measured in terms of convenience, either to the patient or the physician. In this situation, side effects that are minor or rare can not be dismissed. Until it can be shown, beyond any reasonable doubt, that there are absolutely no negative side effects produced as the result of elective induction of labor, the procedure should not be used in routine obstetrical care.

To summarize, elective induction of labor appears to be a common obstetrical practice and it appears to introduce risk to the baby and to the mother. Given the current situation, I think there are two courses of action that this subcommittee might pursue: 1) promote research on the unanswered questions in this area, and 2) maximize the dissemination of currently available information so that informed decisions can be made by parents. With respect to the first, it is clear that there are a large number of unanswered questions. For example, we do not know the full magnitude of the incidence of elective induction. I recommend that this subcommittee see that adequate money and resources are available to allow researchers to adequately monitor the incidence and safety of elective induction techniques. This must include surveillance of rare, but serious, side effects.

It is also critical that prospective parents be kept informed of current research in this area. It is parents who must ultimately decide if the convenience is worth the risk. At present, most parents are not in a position to make an informed decision, and, thus, mechanisms are needed to increase the information available to them. Public hearings, such as this one, are one such mechanism. Another way would be to require a signed consent form before an elective induction. The consent form would outline the potential risks. It should be simple, clear, and understandable. Since it is an elective procedure, the consent form should be signed at least 12 hours before the actual procedure takes place.

D. Acknowledgements

While I take full responsibility for the comments in this statement, I would like to acknowledge the help I have received over the past three years from various individuals and institutions. The following individuals, in alphabetical order, co-authored one or more papers reporting our research. They worked on this project in addition to their regular duties:

Elizabeth Cappock
Systems Development Division
Statistics Canada
Ottawa, Ontario
Canada

Steven L. Gortmaker
Department of Health Services
Harvard School of Public Health
Boston, Massachusetts 02115

Judith L. Ladinsky
Department of Preventive Medicine
Center for Health Sciences
University of Wisconsin-Madison
Madison, Wisconsin 53706

A. S. Macpherson
Montreal General Hospital
Montreal, Quebec
Canada

Victor Marshall
Department of Sociology
McMaster University
Hamilton, Ontario
Canada

I would also like to acknowledge the help received from the Department of Sociology, University of North Carolina; Carolina Population Center, University of North Carolina; and the Center for Demography and Ecology, University of Wisonsin.

Senator **Kennedy**. The results of your study conclude that electrive induction is widespread, and there is no medically justifiable reasons for it, and the dimensions of this procedure in this country should be recognized as one with some degree of alarm, by both consumer and——

Dr. **Rindfuss**. Well, the answer to the first question is "Yes." With respect to the second point, by definition elective induction has no medical benefit. It is a residual category.

Senator **Kennedy**. All right.

Ms. Haire.

Ms. **Haire**. First, I would like to thank you for your interest and concern.

I am Doris Haire, chairwoman of the National Women's Health Network, a coalition of women's health groups throughout the United States. I am also president of the American Foundation for Maternal and Child Health and, along with my husband, past co-president of the International Childbirth Education Association, ICEA. The latter organization is the largest patient education group in the United States, reaching 100,000 couples each year through classes for expectant parents.

As an officer of ICEA I have observed obstetric care in 37 countries and throughout the United States. Based on these observations I prepared a report for ICEA entitled "The Cultural Warping of Childbirth," which I would like to submit to the committee as part of the record of these hearings.

I am currently a member of the governing board of the ICEA and am chairwoman of its Committee on Health Law and Regulation.

The educational problems on health care sponsored by these three groups have played a major role in bringing recognition of the fact that many of the practices commonly employed in obstetric care in the United States today are not based on properly controlled scientific data and, while well intentioned, have the potential for placing both the mother and infant at unnecessary risk.

The focus of my concern deals not with those medical procedures and drugs which are necessary for the care of women at risk, but with those same procedures and drugs when they are commonly employed in the care of healthy low-risk mothers during labor and birth.

Emanual Friedman, professor of obstetrics and gynecology, Harvard University School of Medicine, cautioned at a recent medical conference on obstetrics that "95 percent of obstetric practices are based on folklore."

There is no question that the welfare of their patients has always been the genuine concern of American obstetricians. However, like many other segments of American society, obstetricians, on the whole, have tended to overutilize technologic gadgetry, using it indiscriminately to the detriment of many healthy childbearing women and their offspring. A recent editiorial published in Obstetrics and Gynecology, entitled "Technologic Intervention in Obstetrics: Has the Pendulum Swung Too Far?" [1] is evidence that a growing number of health professionals share our concern that unnecessary obstetric drugs and procedures frequently place the mother and her unborn child at risk—risks that the mother might be well unwilling to accept if she were truly informed of those risks. [2] I wonder how many low-risk women would be comforted by ultrasonic monitoring if they were told that no one knows the delayed, long-term effects of ultrasound.

While we commend the American College of Obstetrics and Gynecologists for including in their manual of standards a very clear description of those components which comprise "informed consent," we find little evidence that its members are heeding the recommendations of the ACOG to actually obtain the patient's informed consent. [3] The ACOG apparently has no disciplinary power to penalize a member for unethical practices such as failing to obtain informed consent. It is unfortunate that the only recourse presently available to an obstetric patient who feels that she has been injured or traumatized by her obstetrician's care is to bring a legal action against the obstetrician. Our experience has been that county medical societies tend to be unresponsive to the complaints of woman who protest the actions of their obstetricians. There seems to be no Federal agency in Washington which has the authority or interest in correcting poor obstetric practices, such as:

1. The elective induction of labor.
2. The arbitrary use of uterine stimulants.
3. The routine rupturing of the amniotic membranes in order to speed up labor.
4. Confining the healthy mother to bed during the first stage of labor.
5. Separating the mother from the emotional support of loved one during the stress of childbirth.
6. Applying fundal pressure—external pressure strongly applied to the mother's belly in order to push the baby out of the uterus. This procedure is called in the trade "strong arm forceps."

Episiotomy, an incision in the vagina to widen the vaginal opening, has never been shown by properly controlled evaluation to improve material or infant outcome, nor has it been shown to improve sexual response in either the mother or her consort. Yet tens of millions of American women have been made to accept this painful procedure without any documentation as to its benefits.

I am not able to take the time to include in my verbal testimony the complete list of "routine" or frequently employed obstetric practices which have not been shown by properly controlled evaluation to be in the best interests of mothers and their babies, but I request that the list be included in the record of these hearings. [4]

I would also like to submit for the record a copy of "The Pregnant Patient's Bill of Rights and Responsibilities," which includes most of the ACOG's statement on informed consent and expresses the growing desire of expectant parents to be informed, not only of the known risks of a treatment, but also of the pertinent areas of uncertainty. [5] If there has been no long-term followup on individuals exposed to a drug or procedure in order to determine whether or not there are delayed, long-term effects of that treatment, then expectant parents want to know that. A report on package inserts by Dr. Louis Lasagna, who spoke to this committee last week, indicates that the majority of consumers want to know if there is a risk of death from the use of a drug, even if that risk is only one in every 100,000 cases. [6]

The position paper on family-centered maternity care initiated by the ACOG contained no mention of informed consent and made it evident that the document was prepared without input from health consumer organizations. [7] This is regrettable for the growing number of couples who are rejecting hospital-based obstetric care will not be satisfied by curtains at the window and a rug on the floor as long as these so-called "birth rooms" include mandatory fetal monitoring and IV infusion. These couples will continue to forego the hospital obstetric unit.

In 1971, Dr. Jerold Lucey, then chairman of the committee on Fetus and Newborn of the American Academy of Pediatrics, stated:

> There is still a great deal we do not know about the consequences of various obstetrical practices and aspects of maternity care. . . . Many of our accepted practices are rooted more in hospital and medical tradition than in human physiology. [8]

Dr. Lucey's comment still holds true today.

Like a snowball rolling downhill, American obstetric care has gradually accumulated an ever-increasing amount of obstetric interventive practices which, however well intentioned, have never been shown by properly controlled evaluation to be in the best interests of mothers and their offspring. The process has been so gradual that we have reached a point in obstetric care in this country which is considered barbaric by many European and American health professionals. Childbirth education, which is considered an integral part of good obstetric care in such countries as Sweden and the Netherlands, is considered by many American obstetricians to be a frill rather than essential to a good infant outcome.

Having observed obstetric care in 37 countries, I can say without hesitation that it is no accident that an infant born in the United States is more than twice as likely to die during the first day of life than is an infant born in the Netherlands or Japan—countries where many children are born at home or in maternity homes and where the midwives make a maximum effort to avoid interference in the intricate process of checks and balances of human parturition, even in hospital obstetric units. [9]

It is not my intention to denigrate the accomplishments of American technology in making birth safer for the high-risk mother and her infant. My concern is that the aggressive practices which have become routine in most American obstetric care have made childbirth a traumatic event, often detrimental and, at time, destructive for both the mother and her infant. American women and their offspring have become the victims of misguided kindness. For years, anesthesiologists and obstetricians have been telling healthy mothers that drugs administered to a healthy mother in order to relieve her apprehension, discomfort, or pain during childbirth would actually improve the fetal environment. Only recently did I learn that there is no conclusive evidence which has demonstrated an improvement in infant outcome due to the use of such drugs. The evidence is quite clear that drugs administered to healthy women during pregnancy, labor, and birth by skilled health professionals frequently place the fetus and newborn infant at risk and jeopardize the newborn infant's ability to adjust to extrauterine life.

In direct contrast to past assumption, research by Doering, professor of Sociology of Johns Hopkins University, indicates that the greater the mother's awareness of the physical and emotional sensations of birth, the closer will be her affectional bonding to her infant. [10] Research carried out by Klaus and Kennell strongly indicates that drugs administered to relieve the mother's discomfort and pain during labor and birth tend to adversely affect the establishment of early affectional bonding between the mother and her infant. [11] This has significant implications for family stability and child abuse.

There is no doubt in my mind that at least a large percentage of learning disabled and handicapped children is the result of obstetric practices which interfere with the normal biochemical checks and balances provided by nature to assure the normal progression of labor and a good maternal and infant outcome.

It is estimated that one out of every 35 children born today in the United States will eventually be diagnosed as retarded. In 75 percent of these cases, there is no known familial, socialogic, or physical predisposing factor. [12] One out of every ten U.S. children is learning disabled, [13] and 1 out of every 20 is hyperactive. [14] The estimates vary somewhat according to the source, but the figures are shockingly high even within the range. While the elimination of premature birth should certainly be one of our goals in improving infant outcome we must also come to grips with the fact that prematurity, poverty, and maternal ill health are not the only causes of poor infant outcome. [15] In one large Boston study, 80 percent of the children demonstrating significant brain dysfunction were not premature but were within the normal range of gestational age and weight.[16] Experts now estimate that one out of every three newborn infants admitted to U.S. intensive care nurseries come from mothers who were diagnosed as completely normal when labor began.[17]

Why?

Dr. Nicholas M. Greene, professor of Anesthesiology, Yale University School of Medicine, obviously shared our concern for recently he wrote me:

"Anesthesia during labor and delivery constitutes a demonstrable and significant contributory factor in neonatal brain dysfunction." [18]

Dr. Bradley Smith, former president of the American Society of Anesthesiologists, told an audience of 600 obstetricians and anesthesiologists:

"We now know that drugs we give women during labor and delivery can cause learning disability." [19]

Neonatologist Dr. John Kennell recently cautioned on NBC's Today show that "Virtually everything that is done to a newborn infant is wrong."

Despite these warnings by renowned specialists, we have been unable to find any significant effort being made by any Federal agency to initiate or fund research programs which could help to determine if there is a cause and effect relationship between common obstetric drugs and practices, administered singly or in combination, and subsequent learning disability and neurological dysfunction in the offspring exposed to these drugs and procedures in utero during labor and borth. As a result, millions of American children have been allowed to be exposed to these drugs in utero without scientifically valid, sequential evaluations being carried out on children so exposed. The inadequacy of obstetric records makes it difficult for a school psychologist or pediatric neurologist to determine whether a cholds' dysfunction may be the result of organic damage.

All drugs, no matter how they are taken by or administered to a childbearing woman, have the potential for directly or indirectly adversely affecting the unborn child or its intrauterine environment. Any drug which artifically changes the mother's blood chemistry, initiates labor, shortens the intervals between uterine contractions or increases the length and intensity of the contractions beyond the physiologically normal range, or increases the need for fundal pressure or forcepts extraction can directly or indirectly adversely affect the fetus.

No one knows the degree of drug toxicity, oxygen depletion, fundal pressure or head compression or traction by forceps that an unborn infant can tolerate before he sustains permanent brain damage. The incidence of all these conditions can be increased as a result of various commonly used obstetric-related drugs. Almost without exception, drugs administered to mothers no matter how they are administered to or taken by the mother, rapidly enter the mother's blood stream, pass through the placental membranes and enter the blood stream of the fetus and the brain in a matter of seconds.

There is abundant scientific evidence that many obstetric drugs and practices employed in the care of normal childbearing women interfere with the normal oxygenation of fetal brain cells. [20], [21], [22], [23], [24], [25] Yet there is no apparent effort being made by any Federal agency to coordinate and link up the significant data in order to determine cause and effect.

I am very familiar with the Collaborative Perinatal Study and deplore the fact that the designers of this $150 million study made no effort to include a control group of healthy unmedicated mothers and their offspring, which could have served as a baseline against which to measure deviation from normal. [26]

The Committee on Drugs of the American Academy of Pediatrics has warned that there is no drug which, when taken by or administered to a childbearing woman, has been proved safe for the unborn child. Yet each year millions of unborn and newly born infants are exposed to drugs which have never been proven safe for them.

When I have criticized the FDA's reluctance to investigate the safety of those drugs presently being administered to women during labor and birth, I am usually told by FDA officials that it would be unethical for the agency to permit a drug evaluation to be carried out in pregnant women and their offspring. In other words, the FDA condones the administration of drugs which have never been proven safe for the unborn child, but it deems an evaluation of these drugs, once given, to be unethical.

The FDA Obstetric-Gynecologic Advisory Committee is responsible for evaluation of the safety of a drug not only for the mother but also for the unborn infant. Yet despite letters of protest over the past several years that Committee does not include a single neonatologist, pediatrician, behavioral scientist, or an informed consumer representative.

Few American women—and men, for that matter—realize that the U.S. Food and Drug Administration does not require pharmaceutical manufacturers filing a new drug application to establish the safety of the drug in regard to the drug's delayed or long-term effect on the neuralogic, mental, or physical development of the offspring in order to gain FDA approval as a "safe" drug for use in obstetrics. Nor does the proposed new Drug Regulations Reform Act appear to require such properly controlled evidence of safety in regard to the delayed, long-term effects on the child's subsequent development. Few women realize when they accept a drug prescribed for or administered to them during pregnancy and childbirth that most of the drugs used in obstetrics have never been specifically reviewed and approved by the FDA for use during labor and birth; therefore, no safe dose has been determined by the FDA for the parturient and her unborn baby. There is nothing in the present or proposed FDA regulations which will prevent another DES-like disaster from occurring.

The FDA has also allowed wording in the package inserts which accompany most obstetric drugs to imply that, if there is no immediately observable indication of damage, there is no cause for concern. An unpublished review of 35 studies collected by Dr. Yvonne Brackbill, graduate research professor, Department of Psychology and Department of Obstetrics and Gynecology, University of Florida, whose verbal testimony had to be deleted at the last moment because of time constraints, shows that almost all investigators have found statistically significant adverse effects of obstetrical medication on infant behavior—namely on the ability to see and hear, the development of motor skills, language ability, intelligence, and so on. There is every indication that in many cases these adverse effects persist. I have a statement prepared by Dr. Brackbill for this hearing, and I would like to submit it for the record. Because Dr. Brackbill's testimony relates strongly to my own testimony. Therefore, I request that the testimony Dr. Brackbill had prepared for this hearing be included in the record. [27]

Those research projects which purport to demonstrate the safety of various obstetric procedures and drugs invariably exclude from testing those infants resulting from "unexplained obstetric emergencies." Since many obstetric emergencies are the result of obstetric drugs, the failure to include those infants biases the data. In many instances, the complete criteria for exclusion is not revealed in the final published paper.

It is the contention of the National Women's Health Network and the International Childbirth Education Association that the U.S. Food and Drug Administration does not have properly controlled data to support the assumption of safety which is implied in many of the package inserts. The FDA has failed to adequately protect the public by allowing package inserts to imply that the only risks to be concerned about are those which involved immediately observable damage to the fetus or neonate.

We do not suggest the removal of a drug from the market which has a value. We urge that, whenever appropriate, package inserts carry a cautionary statement to the effect that, "No long-term followup has been carried out on individuals administered—drug name or procedure—or on children who have been exposed in utero to—drug name or procedure—during pregnancy, labor, and birth. Whether or not there may be delayed, long-term adverse effects on physical and neurological development has not been determined."

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research has done little to protect mothers and their unborn children from being used as experimental subjects without the mothers' true informed consent. There is no stipulation in the Commission's recommendations which dictates that the pregnant or parturient woman must be advised in writing that, because the drug or procedure is experimental, there may be delayed, long-term adverse effects on the mother or her offspring which cannot be determined prior to the time the mother receives the treatment.

STEPS TOWARD IMPROVING THE SYSTEM

1. The first and most essential step in achieving a reduction in the steady stream of neurologically impaired infants born in this country each year is to create a National Commission on Maternal and Child Health, to be headed by a behavioral scientist who is knowledgeable in the areas of obstetrics and newborn care. I know of three behavioral scientists, two of them women, who are eminently qualified to head such a commission. This commission should be composed of neonatologists, prediatricians, pediatric pharmacologists, obstetricians, midwives, nurses, ethicists, and knowledgeable lay people. Experts from those countries which consistently have a better infant outcome than we do should be brought in as consultants. There is no Federal organization I know of whose makeup and purpose fills the void in this field.
2. The FDA Obstetric-Gynecologic Advisory Committee should be divided into two committees, one committee focusing on gynecologic matters, the other dedicated to obstetrics.
3. There should be two consumer members with voting rights on each FDA advisory committee.
4. The obstetric patient should have access to her and her baby's medical records, including X-rays, strip charts, drugs prescribed, et cetera. U.S. military personnel have always had access to their health histories and records without adverse consequences.
5. Legislation should be enacted which would guarantee the obstetric patient's right of informed consent in accordance with the principles set forth in the manual of standards of the American College of Obstetricians and Gynecologists. For example, the patient should be given the package insert for all the drugs the physician uses for obstetric care. There is no doubt that women frequently request the drugs administered to them during labor and birth. However, the vast majority of these requests is based on ignorance of the possible consequences rather than on lack of concern for their infants.
6. There is no properly controlled research which has demonstrated that obstetric care for low-risk mothers is safer, more readily available or cheaper in larger obstetric services. In fact, the very reverse is true. [28] A well-controlled study should be carried out to evaluate the benefits and hazards of various approaches to obstetric care in order to compare the effects of these approaches on maternal and infant outcome. A National Institute of Health Services research, which has been proposed in U.S. Senate bill 2466, by Senator Kennedy and his colleagues, would help to make such important evaluations possible.

In closing, I would like to thank the committee for your interest and concern. I would especially like to thank Senator Javits for asking that this hearing be held.

BIBLIOGRAPHY

EXHIBIT A

1. Haire, Doris: "The Cultural Warping of Childbirth," International Childbirth Education Association (ICEA), 1972.

2. Baker, R.: "Technologic Intervention in Obstetrics: Has the Pendulum Swung Too Far?", Obstetrics and Gynecology 51: 241–244, 1978.

3. "Standards for Obstetric-Gynecologic Services," American College of Obstetricians and Gynecologists (ACOG), 1974.

EXHIBIT B

4. Haire, Doris: List of Common Obstetric Practices Which Have Not Been Properly Evaluated as to Their Effects on Maternal and Infant Health.

EXHIBIT C

5. Haire, Doris: "The Pregnant Patient's Bill of Rights," International Childbirth Education Association, 1977.

6. Joubert, P. and Lasagna, L.: "Commentary: Patient Package Inserts", Clinical Pharmacology and Therapeutics 18: 507–513, 1975.

7. Position Paper on Family-Centered Maternity Care, American College of Obstetricians and Gynecologists, 1976.

8. Lucey, Jerold, Chairman, Committee on Fetus and Newborn, American Academy of Pediatrics, 1971.

9. Statistics from the United Nations Statistical Office, 1967.

10. Doering, S. and Entwisle, D.: "Preparation during Pregnancy and Ability to Cope with Labor and Delivery", American Journal of Orthopsychiatry 45: 825–837, 1975.

11. Klaus, M. and Kennell, J.: Unpublished data.

12. Brochure, National Association for Retarded Citizens.

13. Personal Communication with the U.S. Office of Education.

14. O'Malley, J. E.: "The Hyperkinetic Syndrome", *Minimal Cerebral Dysfunction in Children*, Grune and Stratton, Inc., 1973.

15. Wegman, M.: "Annual Survey of Vital Statistics—1974", Pediatrics 56: 960–966, 1975.

16. Drorbaugh, J. et al: "Association Between Gestational and Environmental Events and Central Nervous System Function in 7-Year-Old Children", Pediatrics 56: 529–537, 1975.

17. James, L. Stanley: Presentation to National Foundation March of Dimes, New York, 1976.

18. Greene, Nicholas: Personal Communication to Doris Haire.

19. Smith, Bradley: State University of New York (Rochester) Obstetric Conference, 1976.

20. Stookey, R. et al: "Abnormal Contraction Patterns in Patients Monitored during Labor", Obstetrics and Gynecology 42: 359–367, 1973.

21. Schwarcz, R. et al (and Caldeyro-Barcia): "Conservative Management of Labor", Proceedings of the VII World Congress of Obstetrics and Gynaecology, Moscow, 1973.

22. Hoult, I. et al: "Lumbar Epidural Analgesia in Labour: Relation to Fetal Malposition and Instrumental Delivery", British Medical Journal 1: 14–16, 1977.

23. Gabbe, S.: "Umbilical Cord Compression Associated with Amniotomy", American Journal of Obstetrics and Gynecology 126: 353–356, 1976.

24. Zador, G. et al: "Pudental Block in Normal Vaginal Deliveries", Acta Obstetricia and Gynaecologica Scandinavica Supplement 34: 51–64, 1974.

25. Morrison, J.: "Metabolites of Meperidine Related to Fetal Depression", American Journal of Obstetrics and Gynecology 115: 1132–1137, 1973.

26. Collaborative Perinatal Study, National Institute of Child Health and Human Development.

EXHIBIT D

27. Brackbill, Y.: "The Long-Term Effects of Obstetric Medication on Cognitive Functioning and Response", presented at the American Foundation for Maternal and Child Health Conference, November 1977.

28. Mehl, L.: "Common Obstetrical Interventions: Their Effect in Low-Risk Populations", presented at American Foundation for Maternal and Child Health Conference, November 1977.

[The exhibits referred to follows:]

Pages 87-129 of the original document are copyrighted and therefore not available. They are not included in the pagination.

The article, "The Cultural Warping of Childbirth," by Doris Haire, was originally published in the Spring, 1972 edition of the ICEA News and has also been reprinted in Environmental Child Health, Vol. 19, 171-191, June (Special Issue) 1973. Available from ICEA Supplies Center, 1414 N.W. 85th St., Seattle, Wash. 98117.

EXHIBIT D

Lasting Behavioral Effects of Obstetric Medication on Children: Research Findings and Public Policy Implications

Yvonne Brackbill
Graduate Research Professor
Departments of Psychology and Obstetrics and Gynecology
University of Florida and University of Florida Medical School
Gainesville, Florida 32611

Statement before the Senate Subcommittee
on Health and Scientific Research

April 17, 1978

Mr. Chairman and Members of the Subcommittee:

My name is Yvonne Brackbill. I am a Graduate Research Professor of Psychology and Obstetrics and Gynecology at the University of Florida.

I thank you for this opportunity to speak about the lasting behavioral effects of obstetric medication on infants and children -- a research area in which I have been involved for the past decade.

Back in the 1960's, one of my graduate students told me that she wanted to do a thesis on the effects on infant behavior of obstetric medication, ie, the anesthetics and analgesics given mothers during labor and delivery. (By behavior, I mean the ability to see and hear, the development of motor skills, language ability, intelligence, and so on.) She explained that she had been bothered by the prospect of brain damage from obstetric medication since her second child was born and that she was motivated by her lingering anger at having been given such medication against her will at the time. I told her I thought the question would already have been thoroughly researched by obstetricians since they had been using anesthesia for delivery for a century and since the question of possible damage was such an obvious one. The graduate student proved me wrong: there was no body of literature on the subject.

The study that she and I conducted was the beginning of systematic research on obstetric medication effects on infant behavior. At present there are some 35 studies on that topic. The investigators are a diverse lot, and the labs are scattered throughout the United States and Great Britain. Nevertheless, the major findings are clear, consistent, and unequivocal. I will summarize these for you. Full documentation is available in the supporting material which I request your permission to insert in the record as part of my statement.

The basis for the problem is this: that human baby's anatomical and physiological development is not complete at the time it is born. Apropos of obstetric medication, there are two very important ways in which the newborn is immature. One concerns the central nervous system. Important areas of brain are still undeveloped at birth. The production and development of neural elements probably continues in the cerebellum for 1.5 years and in the hippocampus for 4.5 years. During this period of rapid brain growth, the brain is especially vulnerable to damage. Also, it is especially easy for toxins to reach the brain in neonates because the so-called "barrier" between blood and brain is immature as well.

The second important way in which the newborn infant is immature, as far as obstetrical medication is concerned, is that the liver and kidney -- the organs most needed for drug metabolism and excretion -- are not fully functional at time of birth.

So, then, the situation is this. The newborn human being is an organism poorly positioned for dealing with drugs. They cross the placenta rapidly. They lodge in brain structures that are still developing and are therefore at high risk to damage. They are not readily transformed to nontoxic compounds since the necessary liver functions are immature. And they are not readily excreted because of inefficient kidney function.

From all these consideration, it would be small wonder if obstetrical medication agents did not inflict some mischief on the infant.

What are the behavioral effects of obstetric medication and how have they been studied? The 35 investigators I mentioned have studied healthy, full term babies who came from low-risk pregnancies and whose deliveries were normal and uneventful. (In this way one avoids confusing the effects of drugs with the effects of pre-existing disease or complications.) Most of the studies have been done on newborns, though a few have seen older babies. The most important study in NIH's Collaborative Perinatal Project, a longitudinal study of over 50,000 children which Congress authorized in the 1950's. Dr. Sally Broman and

I have finished analyzing the results of this study for 3500 of its most healthy babies tested at 4 months, 8 months, and 12 months. We are now analyzing obstetric medication data for the same children tested at 4 years and 7 years.

Looking at the results of all 35 studies, almost all have found statistically significant behavioral effects of obstetric medication. Furthermore, the direction of these effects is uniformly, without exception, toward behavioral degradation and interference with normal function. NO study has ever demonstrated or even suggested that obstetric medication imporves normal functioning.

A second general finding is that obstetric medication effects are more pronounced in some behavioral areas than others. During the first year of life, the strongest effects can be seen in the development of gross motor abilities -- eg, the ability to sit, to stand, and to locomote. They can also be seen in certain emerging cognitive functions, principally the development of inhibitory ability -- eg, the ability to stop responding to redundant signals, to stop crying when comforted, to stop responding to distracting stimuli. During later years, the strongest effects can be seen in the development of language and associated cognitive skills. At all ages, the effects are more clearly visible when tasks are difficult, ie, when they require the child to exert itself, to make an effort, to cope with problems.

A third general finding is that the behavioral effects of obstetric medication are dose-related and potency-related. That is, stronger drugs and larger doses of a single drug produce stronger behavioral effects. For example, general anesthetics have stronger effects than local anesthetics, and local anesthetics have stronger effects than no anesthetic at all.

The most important general finding is that the behavioral effects of obstetric medication are not transient. They persist. Within the age range for which we have data -- 1 day to 7 years -- there is some evidence of decrease for a few drugs. But for other drugs, most notably inhalant anesthetics, the adverse effects are as strong at 4 years as they are at one year. It is difficult to avoid concluding that the damage is permanent. There are more details on adverse drug effects in the documentary material I have filed with you.

Now I will address three issues that help pull these empirical data into the perspective of health policy and planning.

The first of these issues is the increase over the years in obstetric drug administration. There seems to be a widespread misconception among the medical and nonmedical community alike that the number of drugs administered during labor and delivery is decreasing. This is not true. In point of fact, it is increasing. Documentary statistics are described in my appended material. On the whole, I estimate that 95% of births in Unites States hospitals nowadays are medicated. This means 3,500,000 medicated births out of 3,700,000 total births per year. If the average IQ loss per medicated birth is four points, this means 14,060,000 IQ points lost to new U.S. citizens every year. Cummulatively, that figure should put the problem of obstetric medication at the head of the class of national health priorities.

The second important issue to bring to your attention is the question of accountability in monitoring adverse reactions from these drugs and in controlling their distribution for clinical use. The United States does not monitor these or other adverse drug reactions, as Senator Kennedy pointed out last year. Neither does it effectively control the use of drugs commonly used in obstetric medication but never scientifically evaluated for that purpose. The drugs I'm talking about have all been cleared for clinical use by the FDA. However, the research that served as a basis for FDA clearance was carried out on adults. None has been done using infant subjects. Pharmacological test results from adults cannot automatically be extrapolated to infants because the neonate's response to drugs is often qualitatively different. If we insist on administering drugs to infants, the infant itself must be the object of pharmacological study. Nevertheless, such studies are not carried out by the manufacturers of obstetric drugs nor required by the FDA as a precondition for clearing drugs for clinical use.

Who is responsible for this situation? The FDA claims that it is not responsible for policing the uses to which a drug is put. The drug industry claims that it is not responsible for testing a new drug for all potential uses. From the perspective of child health and welfare, the issue of monitoring and controlling obstetric drugs exists in a vacuum of accountability.

The last policy issue to bring to your attention is a consumer issue: who decides what if any drugs a mother will take and how much? The medical community claims that mothers receive medication only when they request it for pain or when there are birth complications. Although there are no data allowing direct evaluation of this claim, there are indirect sources of evidence. (I have summarized these in my documentary material.) Collectively, they indicate that mothers do not receive adequate information on adverse drug reactions, on differences among drug risks, or on alternatives to drugs for relief from pain. They also indicate that women have little voice in deciding which if any drugs they will consume.

For many illnesses today, drug therapy is the only effective therapy. Under these circumstances, there's very little real decision making involved. But pregnancy is not an illness. Childbirth is not an illness. Administering drugs prenatally and perinatally is more often optional than essential, and there is plenty of room for decision making.

One additional point about the mother as decision maker. In a very real way, the physician protects himself/herself by allowing the mother to share in the decision making process: When the mother takes more responsibility for decision making, the physician takes less responsibility and to that extent makes himself/herself less vulnerable to charges of malpractice.

There are remedies for these problems. Among the potential solutions, I submit two basic recommendations for your consideration.

My first recommendation stems from the fact that the mother is a consumer. She must be treated as an intelligent human being, capable of understanding information on drugs when it is written in plain English, capable of evaluating drug risks and benefits, and capable of choosing alternatives to drugs. Furthermore, she has the right to this information -- just as a smoker has the right to know that tobacco is injurious to her/his health. It is currently within the power of the federal government to achieve these goals. The DHEW has two offices to deal with consumer information and education. One is the Office of Health Information and Health Promotion; the other is the soon to be established Office of Health Technology. I recommend that DHEW prepare two versions of obstetric medication information: one appropriate for the consumer and one appropriate for the professional. I further recommend that the information be made available to all consumers through the Office of Health Information and Health Promotion and to all professionals through the Office of Health Technology.

My second recommendation is that you request the FDA to require long term, behavioral testing of new drugs on immature animals prior to drug clearance for clinical use.[1] Let me emphasize each of the key elements in this recommendation. First, immature animals. As I've pointed out, the young organism's response to drugs is often qualitatively different from the adult's and cannot be predicted with certainty from the adult's response to drugs. The second key element is long term. Not all behavioral abnormalities are apparent immediately after birth.

Many behaviors do not develop until later. As I mentioned, it now appears that obstetric medication has adverse effects on language ability; we did not know this previously because all studies had been done on young infants, prior to the age at which they begin to use language.

A third key term is behavioral testing of new drugs. Behavior is the most vital concern in human development and welfare. Our problems as a nation are underachievement in school, criminal acts, breaches of moral conduct, psychotic behavior, socially maladaptive acts. These are behaviors, and they are not equivalent to the physical and physiological measures traditionally used in drug evaluation. Blood gas parameters do NOT predict reading achievement. Apgar score does NOT predict language skills. Respiration rate does NOT predict motor ability. In order to predict such behaviors or to evaluate them, we must collect behavioral data. Behavioral teratologists have established that many substances toxic to the developing central nervous system cause measurable and permanent behavioral abnormalities in the absence of visible structural change or measurable physiological change.

Great Britain and Japan already have legislation requiring that the behavioral teratology of new drugs be studied before the drugs are marketed. The United States leads the world in pharmaceutical research and development. We must regain our leadership in testing drugs for safety and effectiveness to ensure the mental health, physical health, and welfare of our children.

Thank you again, Mr. Chairman and members of the Subcommittee, for this opportunity to speak to you about the lasting behavioral effects of obstetric medication on infants and children.

Footnote

It is possible for the FDA to require long term, behavioral testing of new drugs on immature animals prior to drug clearance for clinical use without additional legislative authorization. The FDA already has available two routes. One route is via the Code of Federal Regulations, vol. 21, section 314.1 (section on reproduction and teratology studies). The second route is by way of the Federal FDA act, which empowers the Secretary of HEW to deny clearance for a new drug on the grounds that testing did not include all those tests which have reasonable applicability and for which methodology is available.

Senator **Kennedy**. We will include all of your testimony in the record. I just have one rather brief area I would like to inquire about.

What advice would you give to pregnant women in this country in terms of the use of drugs for their common ailments, and also in terms of labor? You have spent a lot of time, your foundation has, and reviewed these facts, and made powerful testimony on this. What advice would you give?

Ms. **Haire**. For one thing, I would like to see the PDR, physicians' desk reference, in every home, along with the family Bible. I realize most of the information is written by the manufacturer. I think any information that a woman gets, in addition to that information that she can get from her physician, is to her advantage.

I have a statement that we have asked FDA t include, when appropriate. May I read it?

Senator **Kennedy**. Well, we will be glad to take a look at it. I gather from your basic testimony that you commented on, it is that there is still, in terms of infant mortality rates in this country, a disparity with other countries, being as dramatic as it is, I gather that one of the conclusions is that it is at the whole range of different interventions that take place with the expectant mother.

I gather that is a very important part, that is the whole range of drugs and other kinds of interventions that take place.

Am I correct in terms of your testimony? I am just wondering what guidance you would give expectant mothers in terms of use of these drugs, other factors on the basis of your studies.

Ms. **Haire**. I have five basic questions we tell mothers to ask their physician, because we want this interaction between the mothers and their physician.

First of all, she is often in the hospital, and everyone around her is a stranger.

The first question should be, "Who are you?"

The second should be, "What are you planning to do?" Then ask, "Why are you planning to do it?" and "Will it possibly hurt me or my baby?"

If the answer is "No." Then ask, "Could I see something from the manufacturer that guarantees that this drug or device is safe?"

Now, we know that there is no such data. We know there is no such material from the manufacturer, but it does encourage a dialog.

I have found that most physicians will be honest with the mother when she asks an intelligent question. We have not asked that any drug be removed from the market, but only that the mother be advised in the patient package insert, and that the physician be advised in the physician's package insert, that:

> No long-term followup has been carried out on children exposed in utero to—drug name or procedure—during pregnancy, labor and birth. There may be delayed, long-term adverse effects on physical and neurologic development which cannot be determined at this time.

Senator **Kennedy**. What you are basically saying is be cautious, and take as little as you can?

Ms. **Haire**. Be cautious, ask questions, and do not necessarily consider a drug that is prescribed by your physician to be absolutely safe.

Now, that is an unfortunate position to have to take. But it is true.

Senator **Javits**. Would you yield for one question, and then I am through?

Should you not really say, in your list of questions, if you have any doubt, do not take it?

Mothers can understand that. If you are in doubt, do not do it.

There is nothing a doctor can do to make you do it. If you are in doubt, do not do it.

Ms. **Haire**. Yes.

Senator **Javits**. Thank you.

[The following material was supplied for the record:]

UNIVERSITY OF FLORIDA
GAINESVILLE 32611

DEPARTMENT OF PSYCHOLOGY

April 18, 1978

Senator Edward M. Kennedy
Attention: Dr. Larry Horowitz
Senate Subcommittee on Health and Scientific Research
Room 4220, Dirksen Office Building
1st Street and Constitution Avenue
Washington, D.C. 20510

Dear Senator Kennedy;

Enclosed please find the testimony which I was asked to prepare for the hearings on obstetrics. Since I was informed by Dr. Horowitz that there was no time to present it verbally, I am submitting it to the Congressional Record in this form.

Every statement in my testimony is documented. The documentary material should also be submitted to the Record. That material is as follows:

Butcher, R. E. Two-page statement and references on behavioral teratology. (Enclosed)

Brackbill, Y. In J. D. Osofsky (Ed.), Handbook of Infant Development. New York: Wiley, in press. (A copy of the 114 page manuscript was sent to Mr. Sheridan several weeks ago.)

Brackbill, Y., & Broman, S. Long term effects of obstetrical medication: A report from the NINCDS Collaborative Perinatal Project. Monograph to be submitted for publication. (Dr. Horowitz and Mr. Sheridan may have received this from NIH by now.)

By the way, Commissioner Kennedy was mistaken in asserting that prenatal and perinatal drug administration is decreasing. Please see page four of my testimony and page 24.3 of Brackbill, in press (a copy of which was sent to Commissioner Kennedy last year). Commissioner Kennedy was also mistaken in stating that there are no data on long term drug effects. Together with Dr. Sally Broman, NINCDS, I am analyzing the Collaborative Perinatal Project data for effects at fours years and seven years of anesthetics and several pre-anesthetic medications, including meperidine (Demerol). Data analysis for the first twelve months of life shows that all drugs studied have long term effects, as you will see in the Brackbill and Broman documentary material.

My thanks to you and to the other members of the Subcommittee for interesting yourselves in this vitally important topic. Thank you also for the opportunity of filing my testimony in the Congressional Record.

Sincerely yours,

Yvonne Brackbill

Yvonne Brackbill
Graduate Research Professor

cc: Senator Javits
Commissioner Kennedy
Senator Schweiker

EQUAL EMPLOYMENT OPPORTUNITY AFFIRMATIVE ACTION EMPLOYER

TESTIMONY OF DORIS HAIRE
SENATE HEALTH SUBCOMMITTEE, APRIL 17, 1978
OVERSIGHT HEARING ON OBSTETRICS

I am Doris Haire, Chairwoman of the National Women's Health network, a coalition of women's health groups throughout the United States. I am also President of the American Foundation for Maternal and Child Health and, along with my husband, past co-President of the International Childbirth Education Association (ICEA). The latter organization is the largest patient education group in the United States, reaching 100,000 couples each year through classes for expectant parents. As an officer of ICEA I have observed obstetric care in 37 countries and throughout the United States. Based on these observations I prepared a report for ICEA entitled, "The Cultural Warping of Childbirth," which I would like to submit to the Committee as part of the record of these hearings. I am currently a member of the governing board of the ICEA and am Chairwoman of its Committee on Health Law and Regulation.

The educational programs on health care sponsored by these three groups have played a major role in bringing recognition of the fact that many of the practices commonly employed in obstetric care in the United States today are not based on properly controlled scientific data and, while well intentioned, have the potential for placing both the mother and infant at unnecessary risk.

Emanuel Friedman, Professor of Obstetrics and Gynecology, Harvard University School of Medicine, cautioned at a recent medical conference on obstetrics that, "Ninety-five percent of obstetric practices are based on folklore."

There is no question that the welfare of their patients has always been the genuine concern of American obstetricians. However, like many other segments of American society, obstetricians, on the whole, have tended to overutilize technologic gadgetry, using it indiscriminately to the detriment of many healthy childbearing women and their offspring. A recent editorial published in Obstetrics and Gynecology, entitled "Technologic Intervention in Obstetrics: Has the Pendulum Swung Too Far?", is evidence that a growing number of health professionals share our concern that unnecessary obstetric drugs and procedures frequently place the mother and her unborn child at risk — risks that the mother might well be unwilling to accept if she were truly informed of those risks.

While we commend the American College of Obstetricians and Gynecologists for including in their manual of standards a very clear description of those components which comprise "informed consent," we find little evidence that its members are heeding the recommendations of the ACOG to actually obtain the patient's informed consent. The ACOG apparently has no disciplinary power to penalize a member for unethical practices such as failing to obtain informed consent. It is unfortunate that the only recourse presently available to an obstetric patient who feels that she has been injured or traumatized by her obstetrician's care is to bring a legal action against the obstetrician. Our experience has been that county medical societies tend to be unresponsive to the complaints of women who protest the actions of their obstetricians. There seems to be no federal agency in Washington which has the authority or interest in correcting poor obstetric practices, such as

1. the electric induction of labor,
2. the arbitrary use of uterine stimulants,
3. the routine rupturing of the amniotic membranes in order to speed up labor,
4. confining the healthy mother to bed during the first stage of labor,
5. separating the mother from the emotional support of a loved one during the stress of childbirth,
6. applying fundal pressure (external pressure strongly applied to the mother's belly in order to push the baby out of the uterus) - This procedure is called in the trade "strong arm forceps."

Episiotomy, an incision in the vagina to widen the vaginal opening, has never been shown by properly controlled evaluation to improve maternal or infant outcome, nor has it been shown to improve sexual response in either the mother or her consort. Yet tens of millions of American women have been made to accept this painful procedure without any documentation as to its benefits.

I am not able to take the time to include in my verbal testimony the complete list of "routine" or frequently employed obstetric practices which have not been shown by properly controlled evaluation to be in the best interests of mothers and their babies, but I request that the list be included in the record of these hearings.

I would also like to submit for the record a copy of "The Pregnant Patient's Bill of Rights and Responsibilities," which includes most of the ACOG's statement on informed consent and expresses the growing desire of expectant parents to be informed, not only of the known risks of a treatment but also of the pertinent areas of uncertainty. If there has been no long-term follow-up on individuals exposed to a drug or procedure in order to determine whether or not there are delayed, long-term effects of that treatment, then expectant parents want to know that. A report on package inserts by Dr. Louis Lasagna, who spoke to this committee last week, indicates that the majority of consumers want to know if there is a risk of death from the use of a drug, even if that risk is only one in every one hundred thousand cases.

The position paper on family-centered maternity care initiated by the ACOG contained no mention of informed consent and made it evident that the document was prepared without input from health consumer organizations. This is regrettable for the growing number of couples who are rejecting hospital-based obstetric care will not be satisfied by curtains at the window and a rug on the floor as long as these so-called "birth rooms" include mandatory fetal monitoring and IV infusion. These couples will continue to forego the hospital obsteric unit.

In 1971 Dr. Jerold Lucey, then Chairman of the Committee on Fetus and Newborn of the American Academy of Pediatrics, stated,

> "There is still a great deal we do not know about the consequences of various obstetrical practices and aspects of maternity care.... Many of our accepted practices are rooted more in hospital and medical tradition than in human physiology."

Dr. Lucey's comment still holds true today.

Like a snowball rolling downhill American obstetric care has gradually accumulated an ever-increasing amount of obstetric interventive practices, which, however well intentioned, have never been shown by properly controlled evaluation to be in the best interests of mothers and their offspring. The process has been so gradual that we have reached a point in obstetric care in this country which is considered barbaric by many European and American health professionals. Childbirth education, which is considered an integral part of good obstetric care in such countries as Sweden and the Netherlands, is considered by many American obstetricians to be a frill rather than essential to a good infant outcome.

Having observed obstetric care in 37 countries, I can say without hesitation that it is no accident that an infant born in the U.S. is more than twice as likely to die during the first day of life than is an infant born in the Netherlands or Japan — countries where many children are born at home or in maternity homes and where a maximum effort is made to avoid interference in the intricate process of checks and balances of human parturition, even in hospital obstetric units.

It is not my intention to denigrate the accomplishments of American technology in making birth safer for the high-risk mother and her infant. My concern is that the aggressive practices which have become routine in most American obstetric care have made childbirth a traumatic event, often detrimental, and, at times, destructive for both the mother and her infant. American women and their offspring have become the victims of misguided kindness. For years anesthesiologists and obstetricians have been telling healthy mothers that drugs administered to a healthy mother in order to relieve her apprehension, discomfort or pain during childbirth would actually improve the fetal environment. Only recently did I learn that there is no evidence which has demonstrated an improvement in infant outcome due to the use of such drugs. The evidence is quite clear that drugs administered to healthy women during pregnancy, labor and birth frequently place the fetus and newborn infant at risk and jeopardize the newborn infant's ability to adjust to extrauterine life.

In direct contrast to past assumption, research by Doering, Professor of Sociology of Johns Hopkins University, indicates that the greater the mother's awareness of the physical and emotional sensations of birth the closer will be her affectional bonding to her infant. Research carried out by Klaus and Kennell strongly indicates that drugs administered to relieve the mother's discomfort and pain during labor and birth tend to adversely affect the establishment of early affectional bonding between the mother and her infant. This has significant implications for family stability and child abuse.

There is no doubt in my mind that at least a large percentage of learning disabled and handicapped children is the result of obstetric practices which interfere with the normal biochemical checks and balances provided by Nature to assure the normal progression of labor and a good maternal and infant outcome.

It is estimated that one out of every 35 children born today in the U.S. will eventually be diagnosed as retarded. In 75% of these cases there is no known familial, sociologic or physical predisposing factor. One out of every 10 U.S. children is learning disabled, and one out of every 20 is hyperactive. The estimates vary somewhat according to the source, but the figures are shockingly high even within the range. While the elimination of premature birth should certainly be one of our goals in improving infant outcome we must also come to grips with the fact that prematurity and maternal ill health are not the only causes of poor infant outcome. In one large Boston study 80% of the children demonstrating significant brain dysfunction were not premature but were within the normal range of gestational age and weight. Experts now estimate that one out every 3 newborn infants admitted to U.S. intensive care nurseries come from mothers who were diagnosed as completely normal when labor began.

Dr. Nicholas M. Greene, Professor of Anesthesiology, Yale University School of Medicine, obviously shared our concern for recently he wrote me:

> "Anesthesia during labor and delivery constitutes a demonstrable and significant contributory factor in neonatal brain dysfunction."

Dr. Bradley Smith, former President of the American Society of Anesthesiologists, told an audience of obstetricians and anesthesiologists:

> "We now know that drugs we give women during labor and delivery can cause learning disability."

Neonatologist Dr. John Kennell recently cautioned on NBC's TODAY show that,

> "Virtually everything that is done to a newborn infant is wrong."

Despite these warnings by reknowned specialists we have been unable to find any significant effort being made by any federal agency to initiate or fund research programs which could help to determine if there is a cause and effect relationship between common obstetric drugs and practices, administered singly or in combination, and subsequent learning disability and neurological dysfunction in the offspring exposed to these drugs and procedures in utero during labor and birth. As a result millions of American children have been allowed to be exposed to these drugs in utero without scientifically valid, sequential evaluations being carried out on children so exposed.

All drugs, no matter how they are taken by or administered to a childbearing woman, have the potential for directly or indirectly adversely affecting the unborn child or its intrauterine environment. Any drug which artifically changes the mother's blood chemistry, initiates labor, shortens the intervals between uterine contractions or increases the length and intensity of the contractions beyond the physiologically normal range, or increases the need for fundal pressure or forceps extraction can directly or indirectly adversely affect the fetus.

No one knows the degree of drug toxicity, oxygen depletion, fundal pressure or head compression or traction by forceps that an unborn infant can tolerate before he sustains permanent brain damage. The incidence of all these conditions can be increased as a result of various commonly used obstetric-related drugs. Almost without exception drugs administered to mothers, no matter how they are administered to or taken by the mother, rapidly enter the mother's blood stream, pass through the placental membranes and enter the bloodstream of the fetus in a matter of seconds or minutes.

There is abundant scientific evidence that many obstetric drugs and practices employed in the care of normal childbearing women interfere with the normal oxygenation of fetal brain cells. Yet there is no apparent effort being made by any federal agency to coordinate and link up the significant data in order to determine cause and effect.

I am familiar with the Collaborative Perinatal Study and deplore the fact that the designers of this $150,000,000 study made no effort to include a control group of healthy, unmedicated mothers and their offspring, which could have served as a baseline against which to measure deviation from normal.

The Committee on Drugs of the American Academy of Pediatrics has warned that there is no drug which, when taken by or administered to a childbearing woman, has been proved safe for the unborn child. Yet each year millions of unborn and newly born infants are exposed to drugs which have never been proven safe for them.

When I have criticized the FDA's reluctance to investigate the safety of drugs presently being administered to women during labor and birth I am usually told by FDA officials that it would be unethical for the agency to permit a drug evaluation to be carried out in pregnant women and their offspring. In other words, the FDA condones the administration of drugs which have never been proven safe for the unborn child, but it deems an evaluation of these drugs, once given, to be unethical.

The FDA Obstetric-Gynecologic Advisory Committee is responsible for evaluation of the safety of a drug not only for the mother but also for the unborn infant. Yet despite letters of protest over the past several years that Committee does not include a single neonatologist, pediatrician, behavioral scientist or an informed consumer representative,

Consolidation of Hospitals

It is unfortunate that, in an era when women are protesting the inhumanity of obstetric care, the Federal government has instituted regulations which will, in effect, eliminate small community obstetric services, thus virtually assuring that a large proportion of American women will be used as teaching subjects without their informed consent. While this may not have been the intention of the guidelines we have already seen such effects resulting from the guidelines. There is no properly controlled research which has demonstrated that obstetric care for low-risk mothers is safer, more readily available or cheaper in larger obstetric services. In fact, the very reverse is true.

Few American women (and men, for that matter), realize that the U.S. Food and Drug Administration does not require pharmaceutical manufacturers filing a new drug application to establish the safety of the drug in regard to the drug's delayed or long-term effects on the neurologic, mental or physical development of the offspring in order to gain FDA approval as a "safe" drug for use in obstetrics. Nor does the new Drug Regulations Reform Act appear to require such properly controlled evidence of safety in regard to the delayed, long-term effects on the child's subsequent development. Few women realize when they accept a drug prescribed for or administered to them during pregnancy and childbirth that most of the drugs used in obstetrics have never been specifically reviewed and approved by the FDA for use during labor and birth; therefore, no safe dose has been determined by the FDA for the parturient and her unborn baby.

The FDA has also allowed wording in the package inserts which accompany most obstetric drugs to imply that, if there is no immediately observable indication of damage, there is no cause for concern. However, research carried out by Dr. Yvonne Brackbill, Graduate Research Professor, Department of Psychology and Department of Obstetrics and Gynecology, University of Florida, strongly suggests that the effects of drugs administered to the mother during labor and birth and observed in the early weeks of life can still be observed when these children have reached school age. Dr. Brackbill was to present testimony here this morning, but because of the Committee's time pressures her presentation has been cut from the schedule. Dr. Brackbill's testimony relates strongly to my own testimony. Therefore, I request that the testimony Dr. Brackbill had prepared for this hearing be included in this record.

Those research projects which purport to demonstrate the safety of various obstetric procedures and drugs invariably exclude from testing those infants resulting from "unexplained obstetric emergencies." Since many obstetric emergencies are the result of obstetric drugs the failure to include those infants biases the data. In many instances the complete criteria for exclusion is not revealed in the final published paper.

It is the contention of the National Women's Health Network and the International Childbirth Education Association that the U.S. Food and Drug Administration does not have properly controlled data to support the assumption of safety which is implied in many of the package inserts. The FDA has failed to adequately protect the public by allowing package inserts to imply that the only risks to be concerned about are those which involved immediately observable damage to the fetus or neonate.

We urge that, whenever appropriate, package inserts carry a cautionary statement to the effect that,

> "No long-term follow-up has been carried out on children exposed in utero to ____________________(drug name or procedure) during pregnancy, labor and birth. There may be delayed, long-term adverse effects on physical and neurologic development which cannot be determined at this time."

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research has done little to protect mothers and their unborn children from being used as experimental subjects without the mothers' true informed consent. There is no stipulation in the Commission's recommendations which dictates that the pregnant or parturient woman must be advised in writing that, because the drug or procedure is experimental, there may be delayed, long-term adverse effects on the mother or her offspring which cannot be determined prior to the time the mother receives the treatment.

Steps Toward Improving the System

The first and most essential step in achieving a reduction in the steady stream of neurologically impaired infants born in this country each year is to create a National Commission on Maternal and Child Health, to be headed by a behavioral scientist who is knowledgeable in the areas of obstetrics and newborn care. I know of three behavioral scientists, two of them women, who are eminently qualified to head such a Commission. This Commission should be comprised of neonatologist pediatricians, pediatric pharmacologists, obstetricians, midwives, nurses, ethicists, and knowledgeable lay people. Experts from those countries which consistently have a better infant outcome than we do should be brought in as consultants. There is no federal organization I know of whose makeup and purpose fills the void in this field.

2. The FDA Obstetric-Gynecologic Advisory Committee should be divided into two committees, one committee focusing on matters gynecologic, the other dedicated to obstetrics.

3. There should be two consumer members with voting rights on each FDA advisory committee.

4. The obstetric patient should have access to her and her baby's medical records, including x-rays, strip charts, drugs prescribed, etc. (U. S. military personnel have always had access to their health histories and records without adverse consequences.)

5. Enforcement by law of the patient's right to informed consent should be established. For example, the patient should be given the package insert for all the drugs the physician uses for obstetric care. There is no doubt that women frequently request the drugs administered to them during labor and birth. However, the Vast majority of these requests are based on ignorance of the possible consequences rather than on lack of concern for their infants.

Statement prepared for the Senate Subcommittee
on Health and Scientific Research
by
Richard E. Butcher

Associate Professor of Research Pediatrics and Psychology
Institute for Developmental Research
Childrens Hospital Research Foundation
Cincinnati, Ohio 45229
and
Chairman, Steering Committee
Behavior Teratology Society

April 17, 1978

For many years teratology, the scientific study of intrauterine abnormalities of development, has dealt exclusively with the occurrence of physical abnormality. It has become increasingly obvious, however, that not all the ramifications of in utero injury are represented by physical malformations. There is clear clinical and experimental evidence demonstrating that mental impairments and other developmental disabilities result from prenatal and perinatal exposure to drugs and chemicals and that these handicaps need not be accompanied by external physical signs. A review of the work of behavioral teratologists also demands the conclusion that in contrast to the limited period of susceptibility to physical deformity, the fetus is vulnerable to brain damage throughout the entire period of its gestation. This expanded period of vulnerability in itself dramatically increases exposure to such hazards. Yet we have no system whatsoever for identifying drugs and chemicals which when administered during pregnancy or delivery may permanently impair psychological functioning in the offspring. There are neither human investigations to study behavioral outcomes of pregnancy nor requirements for animal experiments as there are in Britain and Japan where the behavioral teratology of new drugs must be studied before they are marketed. Thus, there is the threat that events during pregnancy and delivery are reducing the intellectual capacity of a sizeable number of children. Because these impairments are not accompanied by physical signs, they are going completely undetected. We need long term clinical and research programs to study the prenatal and perinatal effects on behavior itself of potential teratogens.

Many of you are aware of the difficulty with which thalidomide was identified as a teratogen under circumstances in which the abnormality produced was gross, unique, and obvious at birth. Consider, in light of that history, how small would be the probability of detecting the cause and effect relationships between an agent administered during pregnancy and an impairment in attention or learning ability. Such an impairment would not be an uncommon event, would represent a rather subtle effect, and would be diagnosed almost certainly after the first year of life.[1]

Striking departures from normal developmental patterns have recently been found in children exposed prenatally to the anticonvulsant medications, trimethadione and hydantoin. Were it not that each of these agents produces some minor physical abnormalities, the postnatal mental impairments that are the most frequent and disabling symptoms of in utero exposure would probably not have been discovered.[2,3]

References

(1) Butcher, R.E., Behavioral testing as a method for assessing risk. Environmental Health Perspectives, 18: 75-78, 1976.

(2) Goldman, A.S., & Yaffe, S.J. Teratogen update: fetal trimethadione syndrome. Teratology, 17: 103-106, 1978.

(3) Hanson, J.W. Teratogen update: fetal hydantoin syndrome. Teratology, 13: 185-188, 1976.

UNIVERSITY OF FLORIDA
GAINESVILLE, 32611

DEPARTMENT OF PSYCHOLOGY

April 18, 1978

Senator Richard S. Schweiker
Senate Subcommittee on Health and Scientific Research
Room 6221, Dirksen Office Building
1st Street and Constitution Avenue
Washington, D. C. 20510

Dear Senator Schweiker;

This will confirm what I mentioned to you yesterday after the hearings on obstetrics. Dr. Finkel is incorrect in stating that the Collaborative Perinatal Project's obstetrical drug data are published. They are not.

Together with Dr. Sally Broman, NINCDS, I have been analyzing these data for a subsample of thirty-five hundred of the healthiest babies in the total sample (no-risk pregnancies or deliveries, full term, etc.) in order that the effects of drugs will not be confounded with the effects of pre-existing diseases. The analysis of drug effects during the first twelve months is finished and ready for publication. (This is the Brackbill and Broman reference in your documentary material.) The analysis of drug effects at four years and seven years is currently underway.

The effects of prenatal drug intake in the collaborative perinatal project data has been published (Heinonen, O. P., Slone, D. & Shapiro, S. Birth Defects and Drugs in Pregnancy. Littleton, Mass.: Publishing Sciences Group, 1977). However, in using the entire sample (more than 50,000) the authors confounded drug effects with the effects of pre-existing disease or non-optimal states.

It was a pleasure to meet you, and I greatly appreciate your interest in these data.

Sincerely yours,

Yvonne Brackbill

Yvonne Brackbill
Graduate Research Professor

P.S. Dr. Broman suggests that NINCDS would be happy to send you all of the material relating to obstetrics that has emanated from the Collaborative Perinatal Project data analyses. If you would like this, please call the office of Dr. J. S. Drage, 496-6701.

cc: Commissioner Kennedy
Senator Kennedy
Senator Javits

YB/lsa

EQUAL EMPLOYMENT OPPORTUNITY AFFIRMATIVE ACTION EMPLOYER

Senator Kennedy. Thank you very much.

Doctor Caldeyro-Barcia.

Dr. Caldeyro-Barcia. I would like to make two points.

One is related to fetal monitoring. The main purpose of fetal monitoring during pregnancy and labor is to assess fetal health. Monitors facilitate the early detection of fetal distress and the adoption of appropriate management of the condition before it produces irreversible damage to the fetus.

Fetal monitoring is the continuous observation and recording of biological functions considered to be reliable indicators of the fetal condition.

The indicator most widely used for this purpose is the record of fetal heart rate, FHR, which, in order to be useful to evaluate fetal health, must be accompanied by simultaneous recording of uterine contractions and of fetal movements.

The acid-base balance, $_pH$, and the partial pressure of oxygen, $_pO_2$, in fetal blood are other very reliable indicators of fetal conditions which complement the information supplied by FHR. At the present time, fetal $_pH$ and $_pO_2$ can only be recorded during labor, since invasive methods are required. FHR and fetal movements may also be recorded during pregnancy using noninvasive methods.

Fetal heart rate can be monitored by several methods.

Clinical auscultation, for example, listening to heart beats and counting them during 10 to 15 second intervals.

Heartbeats can be used with a fetoscope. It is very inexpensive equipment, but it is uncomfortable to the mother, the fetoscope should be applied with pressure on the abdomen of the mother until contacting the fetus. It is a tiring procedure for the obtetrician, and errors are made.

Auscultation becomes much easier with an ultrasound Doppler system ($800) which produces one sound for each beat of the fetal heart. The instrument is applied without pressure on maternal abdomen, causing no discomfort. The distinct and loud signal is easily heard by the obstetrician, and errors in counting are greatly reduced.

Graphical recording of FHR. Fetal monitors produce a tracing of FHR on paper. The absolute value of FHR and the changes throughout time can be easily read and measured. The cardiotachometer, which automatically calculates the FHR, must be triggered by a signal originated in each beat of the fetal heart. Three signals are employed;

The sounds produced by the beat of the fetal heart, phonocardiogram. This method is completely harmless, but it fails to produce accurate records in a high proportion of patients.

The signal generated by an ultrasound beam reflected on the heart which moves with each beat (Doppler principle). There is no evidence that the ultrasounds employed in this method have any undesirable effects on the fetus.

The R wave of fetal electrocardiogram, ECG, which is a very clean and sharp signal, triggers the tachometer, produces very accurate records of FHR.

The phon and ultrasound systems have the advantage of being noninvasive (signal can be obtained with receptors applied to the skin of the maternal abdomen). They can be used throughout pregnancy and labor. They are less accurate than the ECG.

The ECG provides a very accurate record of FHR. It can be easily obtained by inserting an electrode under the skin of the fetal scalp (invasive method). This can be done only during labor, and the membranes need to be ruptured artificially in order to reach the fetal scalp. Although infrequent, some cases have been reported with infection or bleeding in the scalp where the electrode was inserted.

The fetal ECG can be obtained with electrodes applied on the maternal abdomen. This method combines the advantages of being noninvasive and very accurate. However, a high proportion of failure in obtaining the record occurs.

Graphical recording of uterine contractions. This can be obtained by several methods.

External receptor (Tokodynanometer) applied on the maternal abdomen over the uterus. It perceives the hardening of the uterine wall during each contraction. This method can be employed during pregnancy or labor. It is noninvasive method but only gives accurate information on the frequency of uterine contractions. It gives no quantitative information on the intensity of contractions or uterine tonus (see next paragraph).

Internal methods (invasive). They record the uterine pressure. They give accurate information on the pressure developed by each uterine contraction (intensity) and of the pressure in the uterus between contractions (tonus).

The intrauterine pressure is recorded with electronic pressure transducers connected with thin tubes (catheters) which are introduced into the uterine cavity.

The catheter is introduced into the amniotic cavity through the vagina and the uterine cervix. This requires rupturing the membrane of the orifice of the uterine cervix. This method is employed during labor only.

The catheter is introduced into the amniotic cavity through a needle inserted through the adbdominal wall and uterine wall—aminocentesis—to obtain samples of amniotic flund. After the sample is obtained the catheter is threaded through the needle. This method is empoyed in "high-risk" pregnancies where the composition of the amniotic fluid supplies very useful information on the health and maturity of the fetuse.

The catheter is introduced through the vagina and uterine cervix and slipped between the uterine wall and the ovular membrane which are not ruptured. This method is employed only during labor.

GRAPHIC RECORDING OF FETAL MOVEMENTS

This is no single method that will satisfactorily record all fetal movements.

The external tokodynanometer records well very fetal movement which will strike on the areas where the receptor is placed.

The mother perceives some movement, and she can push a button and a signal will be marked on the recording paper in the fetal monitor.

Abdominal papation by the obstetrician may also perceive fetal movements.

During pregnancy, monitoring of the FHR made by the noninvasive methods described can provide most valuable information on fetal health. Associated with the recording of fetal movements made with methods described, the information becomes even more valuable and meaningful.

RESPONSE OF FHR TO FETAL MOVEMENTS

A healthy fetus is moving according to patterns which depend on several factors such as the gestational age, hour of day, feeding of the mother, et cetera. Each fetal movement—or series of movements—causes a transient acceleration of FHR which is easily seen in the record.

The percentage of fetal movements which produce accelerations of FHR is an indication of fetal health. When health deteriorates, there is diminished responses of FHR to fetal movements. When there is no response of FHR to fetal movements, the fetus is very sick and may die in a few days. The fetal movements disappear in the 24 to 48 hours preceding fetal death.

VARIABILITY OF THE BASELINE TRACING OF FHR

In normal fetuses there is much variability. When the baseline tracing remains smooth, flat, and fixed in a given value, the fetus may be in deep sleep. This deep sleep does not last normally for more than 20 to 30 minutes, and the variability of the baseline tracing reappears.

If the flat, smooth, fixed baseline FHR tracing lasts for more than 40 minutes, the fetus is probably sick. To be more certain, the recording should be continued for at least 60 minutes.

The antepartum monitoring methods described are known as the nonstress test. They supply most valuable information with noninvasive methods which cause no discomfort to the mother. She can adopt the most comfortable position—sitting, lying on the side or the back, et cetera.)

To confirm the tentative diagnosis of "sick fetus" made with the tests described the test of fetal tolerance to induced uterine contractions is most useful. Labor-like uterine contractions are produced with intravenous infusion of oxytocin given at appropriate dose per minute. When the fetal health is good, uterine contractions cause no changes in FHR. If fetal health is impaired, each uterine contraction will be followed by a transient fall in FHR known as "type II dip" or late "deceleration." The test is considered positive when three or more out of ten labor-like contractions cause type II dips in FHR tracing.

ADVANTAGES OF ANTEPARTUM FETAL MONITORING

Employing the methods described, it is possible to evaluate the health condition of a given fetus during pregnancy. This technology has produced great progress in perinatal medicine.

In the last decade, attention was focused on the "high risk pregnancy." These were pregnant women in whom, because of certain diseases—diabetes, arterial hypertension, et cetera—or other such factors such as low socioeconomic level, advanced age, et cetera, the fetus had higher probabilities of becoming sick, not growing adequately, or even dying.

Today it is possible to be more precise and diagnose directly what is the health condition of a given fetus with very little error. Those fetuses requiring special care can be pinpointed and have concentrated on them the available resources for preventing further deterioration.

The use of other diagnostic methods, such as ultrasound echography, has greatly increased the accuracy in the diagnosis of the intrauterine patient.

NEED FOR CONTINUOUS ELECTRONIC MONITORING OF THE FETUS

Because of the added stress of uterine contractions during labor, the condition of the fetus may deteriorate very rapidly.

In the already sick fetus, diagnosed by antepartum monitoring, continuous electronic monitoring of fetal heart rate and uterine contractions is indispensable, since it gives a continuous flow of information enabling a very close supervision of the fetus.

"High risk" pregnancies, in which antepartum monitoring has not detected signs of impaired fetal health, require less close attention. However, this group should be monitored throughout labor.

In "therapeutic induction" of labor, fetal monitoring is indispensable because (*a*) the induction is performed in a "high risk pregnancy" which may have a "sick fetus"; (*b*) it is important to monitor the intensity, frequency, and tone of uterine contractions, to adjust the dose of oxytocin necessary to promote the progress of labor without jeopardizing the fetus.

ADVANTAGE OF INTRAPARTUM FETAL MONITORING

It is the most reliable method for making early diagnosis of fetal distress and applying the appropriate corrective measures before irreversible damage is produced to the fetus.

DISADVANTAGES OF INTRAPARTUM FETAL MONITORING

One inconvenience with the method presently employed for monitoring is that the parturient woman has to remain quiet, usually in bed, during labor. Several investigations have shown the advantage of having the mother moving freely as she wishes, standing, walking, and sitting. The upright position is preferred by the parturient women because they feel more comfortable and less pain is perceived than in the recumbent position.

Telemetry systems will be most useful to transmit the signal from a parturient woman who is moving freely to the fetal monitor.

Several papers have been published—Haverkamp, et al., Renous, et al.—on "high risk" pregnancies showing that with good clinical auscultation of the fetal heart rate, the results of labor management are as good as with electronic fetal monitoring and pH measurements in fetal blood. Such types of prospective randomized studies are excellent for giving us the proper value of fetal monitoring.

Fetal monitoring should not interfere with natural spontaneous labor. Membrane should not be ruptured with the purpose of inserting an electrode in the fetal scalp. Only if with noninvasive methods signs of alarm appear is it justified to rupture the membrane and insert a scalp electrode.

If the tracing of FHR thus obtained confirms the diagnosis of fetal distress, blood sampling from the fetal scalp should then be obtained.

All these technologies are not incompatible with a homelike environment, where the parturient woman can receive the moral support of her husband, and other members of the family.

Pain-relieving medication, sedatives, and anesthesia should be used only when indispensable. The fully-awake mother should have an active participation and enjoy the event of having a child start an early interaction with the neonate. These are some of the biological bases of family unity and happiness.

Breast feeding should start as early as possible after birth, and the neonate should remain with its mother with as much an emotional and physical interaction as possible.

Next I will discuss elective induction of labor, advantages and disadvantages.

DEFINITION

The electric induction of labor is started at a previously set date and hour. The time is set according to the availability of the obstetrician or of the perinatal team—obstetrician, neonatologist, nurse-midwife, anesthesiologist—which should be present during the induction.

The availability of labor and delivery rooms, monitors, infusion pumps for oxytocin and other necessary equipment, is another factor taken into account when setting the time for starting the elective induction.

The presence in the hospital of the pregnant women—especially for those women living in isolated distant areas—may be another factor.

The "elective" induction should be performed only in pregnant women who have reached the term of gestation—more than 38 complete weeks since the last menstrual period. The fetus should be mature for birth and in good health.

"Therapeutic" induction is indicated when continuation of pregnancy may increase fetal and/or maternal mortality or morbidity. The increased risk usually results from impaired maternal and/or fetal health. Examples of the condition are maternal diabetes, arterial hypertension and proteinuria, Rh incompatability, pregnancy prolonged beyond the 42d week, et cetera. The alternative choice to "therapeutic" induction is cesarean section. Therapeutic induction will not be discussed in the present report.

METHODS

Elective induction is usually accomplished by two procedures which may be employed separately or jointly in the same women.

Artificial rupture of the membranes or amniorrhexis.

Amniorrhexis is not advisable because:

(*a*) It increases the risk of intrauterine infection, neonatal, and maternal sepsis.

(*b*) It deprives the fetal head from the natural hydraulic protection provided by the amniotic fluid present inside the membranes. It increases the mechanical trauma exerted on the fetal head.

(*c*) It also deprives the umbilical cord of a similar protection, especially when there are loops of the cord around the fetal neck, which are present in 25 percent of labors. This lack of protection facilitates the compression of the umbilical vessels between the contracting uterus and the fetus. The prolonged occlusion of umbilical vessels causes fetal hypoxia.

Administration of an oxytocic; that is, a substance which stimulates the production of labor-like contractions in the uterine muscle. Oxytocin—trade names "Pitocin," "Syntocinon," et cetera—is the most widely employed substance. The best and safest method is continuous intravenous administration—infusion. In a woman at term pregnancy, the dose required to produce uterine contractions similar to those of normal labor is between one and eight miliUnits per minute. The dose has to be adjusted according to the response of the uterus—contractions—of each patient. Once the adequate dose has been reached, it should be maintained without change. Iverdisage should be carefully avoided because it might produce fetal damage—hypoxia. The safest method to be sure that the dose per minute is kept constant is to employ electrical infusion pumps.

The "drip" method does not guarantee against undesirable changes in the dose per minute. It requires periodical supervision. Uterine contraction and fetal heart rate should be continuously recorded with monitors. The dose per minute of oxytocin should be adjusted according to the response of the uterus and to the tolerance of the fetus to uterine contractions. These adjustments require the permanent surveillance of a well-trained professional—obstetrician, nurse-midwife.

Oxytocin is also being used in the form of buccal tablets—oxytocin cytrate. This method is not advisable because the dose absorbed cannot be controlled as accurately as when intravenous infusion with an electric pump is employed. Prostaglandin-F-2-alpha has been employed in the last 5 years instead of oxytocin.

DISADVANTAGES OF ELECTIVE INDUCTION

These disadvantages will be discussed comparing elective induction with normal labor starting spontaneously at term pregnancy.

MATURITY OF THE FETO-MATERNAL UNIT

In normal conditions, labor starts spontaneously when both the fetus and the mother are "ripe" for parturition.

The normal mature fetus is able to successfully adapt to extrauterine life. In "elective" inductions of labor, an increased proportion of premature neonates has been reported. Prematurity is the main cause of neonatal mortality, morbidity, and long-term sequelae among survivors, particularly damage to the central nervous system. Prematurity can be prevented by proper assessment of fetal maturation before indication of elective induction.

Softening of the maternal birth canal. When labor starts spontaneously, the mother is "ripe" for labor and the birth canal has become soft and is more easily opened to permit the passage of the fetus. This softening includes the uterine cervix, the vagina, and perineum as well as the joints between pelvic bones. The softened birth canal opposes less resistance to dilatation.

One beneficial consequence is that less "uterine work"—accumulative addition of the pressure developed by uterine contractions—is needed to accomplish cervical dilatation.

With softened joints between pelvic bones, less bearing down efforts are needed for the delivery of the fetal head.

Risk of fetal hypoxia. Each uterine contraction and bearing down effort is a potential cause of fetal hypoxia. The risk augments as uterine contractions are stronger and the interval between them becomes shorter, and also as the total number of contractions increases.

In elective inductions there is increased risk of fetal hypoxia because uterine contractility is greater than in spontaneous labor.

In addition, a greater incidence of prolapse of the umbilical cord has been reported in elective inductions of labor, particularly when amniorrhexis is performed as the first maneuver for inducing labor. Prolapse of the umbilical cord is a severe complication which facilitates the occlusion of umbilical vessels and fetal hypoxia.

Risk of trauma to the fetal head. This risk is increased in elective induction because:

(*a*) The birth canal may not be softened.

(*b*) The head is deprived of the natural hydraulic protection.

(*c*) The total number of uterine contractions and the total uterine "work" are greater.

RISK OF FETAL DEATH

Fetal deaths related to elective induction have been reported to be 0.7 percent, which is higher than that in a similar group of spontaneously starting labor at term. Other studies claim that in elective induction, perinatal mortality is lower than what one might expect in spontaneous labor.

Increased incidence of neonatal jaundice. Several authors have reported that the incidence of neonatal jaundice is greater after elective induction than after spontaneous labor.

Long-term outcome of child development. Four-year followup studies have been unable to substantiate that elective induction of labor increases the risk of brain damage when the fetus is mature.

Since unsuspected prematurity of the infant is an acknowledged risk of elective induction, and immaturity of the infant is associated with an increased risk of brain damage, inclusion in this study of the premature infants born of induced labors would be likely to have altered our conclusion. These observations emphasize the need for a prospective study of elective induction with controls selected from the same population as the induced patients. No other methodology is likely to dispel the haziness surrounding the risks of fetal morbidity associated with the elective induction of labor.

In elective inductions, the intensity and frequency of uterine contractions produced with oxytocin infusion are usually greater than in a similar group of spontaneous labors. This fact has been found in retrospective analyses of monitored labors made in our center. This finding is surprising since, in our center, there are strict regulations to administer the lowest amount of oxytocin needed to induce labor. This fact might explain that several authors have reported that the duration of labor in elective inductions is shorter than in spontaneous labor. Each uterine contraction is a potential aggression to the fetus. The stronger the contraction and the shorter the interval between contractions, the greater the risk of fetal hypoxia.

Complexity and costs. Elective induction is a more complex and expensive procedure than the management of spontaneous labor.

To minimize adverse effects on the fetus, in all inductions of labor the intensity and frequency of uterine contractions and their effect on the fetal heart rate should be continuously recorded. These records are obtained with fetal-labor monitors. Personnel well trained in the interpretation of such records should be present.

Oxytogin should be administered with infusion pumps in order to avoid accidental changes of the dose per minute and to prevent overdose of oxytocin, which is one of the most frequent causes of fetal hypoxia during induced labor.

Advantages of elective induction of labor: These advantages are of a circumstantial nature and related to the present status of perinatal care.

Availability of the professional perinatal team when elective induction of labor occurs. If the maternity hospital does not have a well-trained perinatal team 24 hours per day and 7 days per week, spontaneous labor may start and delivery occur at a time—night, weekend—when good professional care is not available, and perinatal "risk" is increased because of inadequate management of labor or of the neonate. Since "elective" induction is started when the necessary personnel are available, this source of risk is prevented. The rational solution is a system of regionalized, progressive perinatal care.

Another indication for elective induction is a pregnant women at term who lives in a geographically isolated area. A better solution is the use of "maternal homes" with a low daily cost per bed, very near the maternity hospital, where the pregnant woman at term may stay—supervised by nurses—until labor starts spontaneously.

Senator KENNEDY. Thank you very much. You have spent a lot of time on these issues.

The international reputation from your testimony is well deserved, and we very much appreciate your presence here and your comments.

Senator JAVITS. May I just thank the doctor for appearing? It is unusual that we have non-U.S. witnesses, and it is something of a risk to expose yourself, Doctor, to the cross examination of Senators. I would like to thank you very much for your admittedly high expertise in this field, giving us the benefit.

Senator KENNEDY. You share the concern of other members of the panel with regard to elective induction. This ought to be a concern not only for American medicine, but generally medicine throughout the world, as I understand it.

Dr. CALDEYRO-BARCIA. Yes, at least in what is considered the civilized world, and I think just by changing the organization of prenatal care, the need for elective induction will disappear.

[Material supplied for the record follows:]

ELECTIVE INDUCTION OF LABOR:

ADVANTAGES AND DISADVANTAGES

Report submitted to the Sub-Committee
on Health of the Senate of
the United States of America

April 17, 1978

prepared by

Roberto Caldeyro-Barcia, M.D., F.A.C.O.G. (Hon), F.A.C.S. (Hon)
Director
Latin American Center of Perinatology and Human Develoment,
Pan American Health Organization (PAHO)

Address: Hospital de Clínicas, piso 16
Montevideo, Uruguay

Mail Address: Casilla de Correo 627
Montevideo, Uruguay

Dr. Caldeyro-Barcia has been duly authorized by the Director of PAHO to present this testimony. The opinions stated in this document belong to the author and should not be taken as the view of PAHO.

Dr. Caldeyro-Barcia is President of the International Federation of Gynecology and Obstetrics (FIGO).

The Executive Board of FIGO has given authorization to Dr. Caldeyro-Barcia to present this testimony. The opinions stated in the document belong to the author and do not reflect the views of FIGO.

ELECTIVE INDUCTION OF LABOR

1. Definition and Methods

1.1 Definition. The elective induction of labor is started at a previously set date and hour. The time is set according to the availability of the obstetrician or of the perinatal team (obstetrician, neonatologist, nurse-midwife, anesthesiologist) which should be present during the induction (see paragraph 3.1.). The availability of labor and delivery rooms, monitors, infusion pumps for oxytocin (see paragraph 2.3) and other necessary equipment, is another factor taken into account when setting the time for starting the elective induction.

The presence in the hospital of the pregnant women (especially for those women living in isolated, distant areas) may be another factor (see paragraph 3.1.2).

The "elective" induction should be performed only in pregnant women who have reached the term of gestation (more than 38 complete weeks since the last menstrual period). The fetus should be mature for birth and in good health.

"Therapeutic" induction is indicated when continuation of pregnancy may increase fetal and/or maternal mortality or morbidity. The increased risk usually results from impaired maternal and/or fetal health. Examples of the condition are maternal diabetes, arterial hypertension and proteinuria, Rh incompatibility, pregnancy prolonged beyond the 42nd week, etc. The alternative choice to "therapeutic" induction is cesarean section. Therapeutic induction will not be discussed in the present report.

1.2 Methods. Elective induction is usually accomplished by two procedures which may be employed separately or jointly in the same woman.

1.2.1 Artificial rupture of the membranes or amniorrhexis. Amniorrhexis is not advisable because:

(a) It increases the risk of intrauterine infection, neonatal and maternal sepsis.

(b) It deprives the fetal head from the natural hydraulic protection provided by the amniotic fluid present inside the membranes. It increases the mechanical trauma exerted on the fetal head. (3, 4, 16, 17)

(c) It also deprives the umbilical cord of a similar protection, especially when there are loops of the cord around the fetal neck, which are present in 25% of labors. This lack of protection facilitates the compression of the umbilical vessels between the contracting uterus and the fetus. The prolonged occlusion of umbilical vessels causes fetal hypoxia. (3, 4, 16, 17)

1.2.2 Administration of an oxytocic, i.e., a substance which stimulates the production of labor-like contractions in the uterine muscle. Oxytocin (trade names "Pitocin", Syntocinon", etc.) is the most widely employed substance. The best and safest method is continuous intravenous administration (infusion). In a woman at term pregnancy the dose required to produce uterine contractions similar to those of normal labor is between 1 and 8 miliUnits per minute. The dose has to be adjusted according to the response of the uterus (contractions) of each patient. Once the adequate dose has been reached, it should be maintained without changes. Overdosage should be carefully avoided because it might produce fetal damage (hypoxia) (see paragraph 2.1.2.3). The safest method to be sure that the dose per minute is kept constant is to employ electrical infusion pumps (see paragraph 2.3.2).

The "drip" method does not guarantee against undesirable changes in the dose per minute. It requires periodical supervision. Uterine contraction and fetal heart rate should be continuously recorded with monitors. The dose per minute of oxytocin should be adjusted according to the response of the uterus and to the tolerance of the fetus to uterine contractions. These adjustments require the permanent surveillance of a well-trained professional (obstetrician, nurse-midwife).

Oxytocin is also being used in the form of buccal tablets (oxytocin cytrate). (5) This method is not advisable because the dose absorbed cannot be controlled as accurately as when intravenous infusion with an electric pump is employed. Prostaglandin-F-2-alpha has been employed in the last five years instead of oxytocin. (2, 13)

2. Disadvantages of Elective Induction.

These disadvantages will be discussed comparing elective induction with normal labor starting spontaneously at term pregnancy.

2.1 Maturity of the feto-maternal unit. In normal conditions labor starts spontaneously when both the fetus and the mother are "ripe" for parturition.

2.1.1 The mature normal fetus is able to successfully adapt to extrauterine life. In "elective" inductions of labor, an increased proportion of premature neonates has been reported.(10, 11) Prematurity is the main cause of neonatal mortality, morbidity and long-term sequelae among survivors, particularly damage to the central nervous sytem. Prematurity can be prevented by proper assessment of fetal maturation before indication of elective induction.

2.1.2 Softening of the maternal birth canal. When labor starts spontaneously the mother is "ripe" for labor and the birth canal has become soft and is more easily opened to permit the passage of the fetus. This softening includes the uterine cervix, the vagina and perineum as well as the joints between pelvic bones. The softened birth canal opposes less resistance to dilatation.

2.1.2.1 One beneficial consequence is that less "uterine work" (accumulative addition of the pressure developed by uterine contractions) is needed to accomplish cervical dilatation. (15)

2.1.2.2 With softened joints between pelvic bones, less bearing down efforts are needed for the delivery of the fetal head.

2.1.2.3 Risk of fetal hypoxia. Each uterine contraction and bearing down effort is a potential cause of fetal hypoxia. The risk augments as uterine contractions are stronger and the interval between them becomes shorter (see paragraph 2.2.), and also as the total number of contractions increases (see paragraph 2.1.2.1).

In elective inductions there is increased risk of fetal hypoxia because uterine contractility is greater than in spontaneous labor (see paragraph 2.2).

2.1.2.4 In addition, a greater incidence of prolapse of the umbilical cord has been reported in elective inductions of labor, (10, 11) particularly when amniorrhexis is performed as the first maneuver for inducing labor. Prolapse of the umbilical cord is a severe complication which facilitates the occlusion of umbilical vessels and fetal hypoxia.

2.1.2.5 Risk of trauma to the fetal head. This risk is increased in elective induction (15) because:

a) the birth canal may not be softened (see paragraph (2.1.2);

b) the head is deprived of the natural hydraulic protection (see paragraph 1.2.1);

c) the total number of uterine contractions and the total uterine "work" are greater (paragraph 2.2.1).

2.1.2.6 Risk of fetal death. Fetal deaths related to elective induction have been reported to be 0.7% (11) which is higher than that in a similar group of spontaneously starting labor at term. Other studies claim that in elective induction, perinatal mortality is lower than what one might expect in spontaneous labor (7, 8).

2.1.2.7 Increased incidence of neonatal jaundice. Several authors have reported that the incidence of neonatal jaundice is greater after elective induction than after spontaneous labor (2, 6, 9).

2.1.2.8 Long-term outcome of child development. Four-year follow-up tudies have been unable to substantiate that elective induction of labor increases the risk of brain damage when the fetus is mature. (12)
"Since unsuspected prematurity of the infant is an
"acknowledged risk of elective induction, and imma-
"turity of the infant is associated with an increased
"risk of brain damage, inclusion in this study of the
"premature infants born of induced labors would be
"likely to have altered our conclusion. These obser-
"vations emphasize the need for a prospective study
"of elective induction with controls selected from the
"same population as the induced patients. No other
"methodology is likely to dispel the haziness surround-
"ing the risks of fetal morbidity associated with the
"elective induction of labor." (12)

2.2 In elective inductions, the intensity and frequency of uterine contractions produced with oxytocin infusion are usually greater than in a similar group of spontaneous labors. This fact has been found in retrospective analyses (15) of monitored labors made in our Center*. This finding is surprising since in our Center there are strict regulations to administer the lowest amount of oxytocin needed to induce labor. This fact might explain that several authors (10,11)have reported that the duration of labor in elective inductions is shorter than in spontaneous labor. Each uterine contraction is a potential aggression to the fetus. The stronger the contraction and the shorter the interval between contractions, the greater the risk of fetal hypoxia.

---

*Latin American Center of Perinatology

2.3 Complexity and costs. Elective induction is a more complex and expensive procedure than the management of spontaneous labor.

2.3.1 To minimize adverse effects on the fetus, in all inductions of labor the intensity and frequency of uterine contractions and their effect on the fetal heart rate should be continuously recorded. These records are obtained with fetal-labor monitors. Personnel well trained in the interpretation of such records should be present.

2.3.2 Oxytocin should be administered with infusion pumps in order to avoid accidental changes of the dose per minute and to prevent overdose of oxytocin, which is one of the most frequent causes of fetal hypoxia during induced labor.

3. Advantages of Elective Induction of Labor

These advantages are of a circumstantial nature and related to the present status of perinatal care.

3.1 Availability of the professional perinatal team when elective induction of labor occurs. If the Maternity Hospital does not have a well-trained perinatal team 24 hours per day and seven days per week, spontaneous labor may start and delivery occur at a time (night, weekend) when good professional care is not available, and perinatal "risk" is increased because of inadequate management of labor or of the neonate. Since "elective" induction is started when the necessary personnel are available,this source of risk is prevented. The rational solution is a system of regionalized, progressive, perinatal care.

3.2 Another indicationfor elective induction is a pregnant woman at term who lives in a geographically isolated area. A better solution is the use of "maternal homes" with a low daily cost per bed, very near the Maternity Hospital, where the pregnant woman at term may stay (supervised by nurses) until labor starts spontaneously.

BIBLIOGRAPHY

1. Bishop, E.H.: Dangers attending elective induction of labor. JAMA 166: 1953, 1958.

2. Calder, A. et al: "Increased Bilirubin Levels in Neonates After Induction of Labour by Intravenous Prostaglandin E or Oxytocin". Lancet, 1339-1342, Dec. 7, 1974.

3. Caldeyro-Barcia, R. et al: "Effects of Rupture of Membrane on Fetal Heart Rate Pattern,"Interna. J. Gynaec. Obstet., 10: 169, 1972.

4. Caldeyro-Barcia, R. et al: "Adverse Perinatal Effects of Early Amniotomy During Labor," in "Modern Perinatal Medicine", L. Gluck, ed., Year Book Medical Publ. Inc., Chicago, Ill., 1974, pp.431-449.

5. Chalmers, J.A. et al: Optimal dosage of buccal oxytocin for the induction of labor. Am. J. Obstet. Gynecol., 111:227, 1971.

6. Davies, D. et al: "Neonatal Jaundice and Maternal Oxytocin Infusion," Brit. Med. J. 3: 476, 1973.

7. D'Esopo, D.A. et al: "Elective Induction of Labor", Am. J. Obst. &Gynec., 89: 561, 1964.

8. Fields, H. et al: "Intravenous pitocin in induction and stimulation of labor. A study of 3754 cases", Obst. & Gynec. 13: 353, 1959.

9. Liston, W. et al: "Dangers of Oxytocin-induced Labour to Fetuses", Brit. Med. J., pp. 606-607, Sept. 7, 1974.

10. Niswander, K.R. et al: "Elective induction of labor", Am.J. Obst. & Gynec., pp. 797-800, 1960.

11. Niswander, K.R. et al: "Hazards of Elective Induction of Labor", Obstet. & Gynec., 22:228-233, 1963.

12. Niswander, K.R. et al: "Developmental Status of Children Delivered Through Elective Induction of Labor: Results of a 4-year follow-up study", Obstet. & Gynec., 27:15-19, 1966.

13. Roux, J.F. et al: "Effect of Elective Induction of Labor with Prostaglandin F_2 and E_2 and Oxytocin on Uterine Contraction and Relaxation", Am.J. Obstet. Gynec., 127:718-722, 1977.

14. Schifrin, B.W.: "Fetal heart rate patterns following epidural anaesthesia and oxytocin infusion during labour", J Obstet Gynaecol Br Commo[illegible], 79: 332, 1972.

15. Schwarcz, R.L. et al: "Fetal and Maternal Monitoring in Spontaneous Labors and in Elective Inductions", Amer. J. Obstet. & Gyn., 120:356-362, 1974.

16. Schwarcz, R.L. et al: "Fetal heart rate patterns in labors with intact and with ruptured membranes", *J. Perinat. Med.*, 1: 153, 1973.

17. Schwarcz, R.L. et al: "Conservative Management of Labor", in: *Recent Progress in Obstetrics and Gynaecology*: Proceedings of the VII World Congress held in Moscow, August 12-18, 1973, Excerpta Medica - Amsterdam, 1974.

FETAL MONITORING

Report submitted to the Sub-Committee
on Health of the Senate of
the United States of America

April 17, 1978

prepared by

Roberto Caldeyro-Barcia, M.D., F.A.C.O.G. (Hon), F.A.C.S. (Hon)
Director
Latin American Center of Perinatology and Human Development,
Pan American Health Organization

Address: Hospital de Clínicas, piso 16
Montevideo, Uruguay

Mail Address: Casilla de Correo 627
Montevideo, Uruguay

Dr. Caldeyro-Barcia has been duly authorized by the Director of PAHO to present this testimony. The opinions stated in this document belong to the author and should not be taken as the views of PAHO.

Dr. Caldeyro-Barcia is President of the International Federation of Gynecology and Obstetrics (FIGO).

The Executive Board of FIGO has given authorization to Dr. Caldeyro-Barcia to present this testimony. The opinions stated in the document belong to the author and do not reflect the views of FIGO.

FETAL MONITORING

1. PURPOSE

The main purpose of fetal monitoring during pregnancy and labor is to assess fetal health. Monitors facilitate the early detection of fetal distress and the adoption of appropriate management of the condition before it produces irreversible damage to the fetus.

2. DEFINITION

Fetal monitoring is the continuous observation and recording of biological functions considered to be reliable indicators of the fetal condition.

The indicator most widely used for this purpose is the record of Fetal Heart Rate (FHR) which, in order to be useful to evaluate fetal health, must be accompanied by simultaneous recording of uterine contractions and of fetal movements.

The acid-base balance (pH) and the partial pressure of oxygen (pO_2) in fetal blood are other very reliable indicators of fetal condition which complement the information supplied by FHR. At the present time, fetal pH and pO_2 can only be recorded during labor, since invasive methods are required. FHR and fetal movements may also be recorded during pregnancy using non-invasive methods.

3. METHODS

3.1 Fetal Heart Rate can be monitored by several methods.

3.1.1 Clinical auscultation, i.e., listening to heart beats and counting them during 10 to 15 second intervals.

3.1.1.1 Heart beats can be heard with a fetoscope. It is very inexpensive equipment, but it is uncomfortable to the mother (the fetoscope should be applied with pressure on the abdomen of the mother until contacting the fetus). It is a tiring procedure for the obstetrician and errors are made.

3.1.1.2 Auscultation becomes much easier with an ultrasound Doppler system ($800.00) which produces one sound for each beat of the fetal heart. The instrument is applied without pressure on maternal abdomen, causing no discomfort. The distinct and loud signal is easily heard by the obstetrician and errors in counting are greatly reduced.

3.1.2 Graphical recording of FHR. Fetal monitors produce a tracing of FHR on paper. The absolute value of FHR and the changes throughout time can be easily read and measured. The cardiotachometer (which automatically calculates the FHR) must be triggered by a signal originated in each beat of the fetal heart. Three signals are employed:

3.1.2.1 The sounds produced by the beat of the fetal heart (phonocardiogram). This method is completely harmless but it fails to produce accurate records in a high proportion of patients.

3.1.2.2 The signal generated by an ultrasound beam reflected on the heart which moves with each beat (Doppler principle). There is no evidence that the ultrasounds employed in this method have any undesirable effects on the fetus.

3.1.2.3 The R wave of the fetal Electrocardiogram (ECG), which is a very clean and sharp signal, triggers the tachometer, producing very accurate records of FHR.

3.1.2.4 The phono and ultrasound systems have the advantage of being non-invasive (signals can be obtained with receptors applied on the skin of the maternal abdomen). They can be used throughout pregnancy and labor. They are less accurate than the ECG.

3.1.2.5 The ECG provides a very accurate record of FHR. It can be easily obtained by inserting an electrode under the skin of the fetal scalp (invasive method). This can be done only during labor, and the membranes need to be ruptured artifically in order to reach the fetal scalp. Although infrequent, some cases have been reported with infection or bleeding in the scalp where the electrode was inserted.

3.1.2.6 The fetal ECG can be obtained with electrodes applied on the maternal abdomen. This method combines the advantages of being non-invasive and very accurate. However, a high proportion of failure in obtaining the record occurs.

3.1.3 Graphical recording of uterine contractions. This can be obtained by several methods.

3.1.3.1 External receptor (tokodynanometer) applied on the maternal abdomen over the uterus. It perceives the hardening of the uterine wall during each contraction. This method can be employed during pregnancy or labor. It is a non-invasive method but only gives accurate information on the frequency of uterine contractions. It gives no quantitative information on the intensity of contractions or uterine tonus (see next paragraph).

3.1.3.2 Internal methods (invasive). They record the uterine pressure. They give accurate information on the pressure developed by each uterine contraction (intensity) and of the pressure in the uterus between contractions (tonus).

The intrauterine pressure is recorded with electronic pressure transducers connected with thin tubes (catheters) which are introduced into the uterine cavity.

3.1.3.2.1 The catheter is introduced into the amniotic cavity through the vagina and the uterine cervix. This requires rupturing the membrane at the orifice of the uterine cervix. This method is employed during labor only.

3.1.3.2.2 The catheter is introduced into the amniotic cavity through a needle inserted through the abdominal wall and uterine wall (amniocentesis) to obtain samples of amniotic fluid. After the sample is obtained the catheter is threaded through the needle. This method is employed in "high-risk" pregnancies where the composition of the amniotic fluid supplies very useful information on the health and maturity of the fetus.

3.1.3.2.3 The catheter is introduced through the vagina and uterine cervix and slipped between the uterine muscular wall and the ovular membranes which are not ruptured. This method is employed only during labor.

3.1.4 Graphic recording of fetal movements. There is no single method that will satisfactorily record all fetal movements.

3.1.4.1 The external tokodynanometer (see 3.1.3.1) records well every fetal movement which will strike on the areas where the receptor is placed.

3.1.4.2 The mother perceives some movement, and she can push a button and a signal will be marked on the recording paper of the fetal monitor.

3.1.4.3 Abdominal palpation by the obstetrician may also perceive fetal movements.

4. ANTEPARTUM MONITORING

During pregnancy, monitoring of the FHR made by the non-invasive methods described in 3.1.2 can provide most valuable information on fetal health. Associated with the recording of fetal movements made with methods described in 3.1.3, the information becomes even more valuable and meaningful.

4.1 Response of FHR to fetal movements. A healthy fetus is moving according to patterns which depend on several factors such as the gestational age, hour of day, feeding of the mother, etc. Each fetal movement (or series of movements) causes a transient acceleration of FHR which is easily seen in the record. The percentage of fetal movements which produce accelerations of FHR is an indication of fetal health. When health deteriorates, there is diminished response of FHR to fetal movements. When there is no response of FHR to fetal movements, the fetus is very sick and may die in a few days. The fetal movements disappear in the 24-48 hours preceding fetal death.

4.2 Variability of the baseline tracing of FHR. In normal fetuses, there is much variability. When the baseline tracing remains smooth, flat and fixed in a given value, the fetus may be in deep sleep. This deep sleep does not last normally for more than 20-30 minutes, and the variability of the baseline tracing reappears. If the flat, smooth, fixed baseline FHR tracing lasts for more than 40 minutes, the fetus is probably sick. To be more certain, the recording should be continued for at least 60 minutes.

4.3 The antepartum monitoring methods described in 4.1 and 4.2 are known as the non-stress test. They supply most valuable information with non-invasive methods which cause no discomfort to the mother. She can adopt the most comfortable position (sitting, lying on the side or the back, etc.).

4.4 To confirm the tentative diagnosis of "sick fetus" made with the tests described in paragraphs 4.1 and 4.2, the test of fetal tolerance to induced uterine contractions is most useful. Labor-like uterine contractions are produced with intravenous infusion of oxytocin given at appropriate dose per minute. When the fetal health is good, uterine contractions cause no changes in FHR. If fetal health is impaired, each uterine contraction will be followed by a transient fall in FHR known as "type II dip" or "late deceleration." The test is considered "positive. when 3 or more out of 10 labor-like contractions cause type II dips in FHR tracing.

4.5 Advantages of antepartum fetal monitoring. Employing the methods described in 4.1, 4.2 and 4.4, it is possible to evaluate the health condition of a given fetus during pregnancy. This technology has produced great progress in Perinatal Medicine.

In the last decade, attention was focused on the "high-risk pregnancy." These were pregnant women in whom, because of certain diseases (diabetes, arterial hypertension, etc.) or other factors such as low socio-economic level, advanced age, etc., the fetus had higher probabilities of becoming sick, not growing adequately or even dying. Today it is possible to be more precise and diagnose directly what is the health condition of a given fetus with very little error. Those fetuses requiring special care can be pinpointed and have concentrated on them the available resources for preventing further deterioration. The use of other diagnostic methods such as ultrasound echography has greatly increased the accuracy in the diagnosis of the intra-uterine patient.

5. INTRAPARTUM MONITORING

5.1 Need for continuous electronic monitoring of the fetus. Because of the added stress of uterine contractions during labor, the condition of the fetus may deteriorate very rapidly.

5.2 In the already "sick fetus" (diagnosed by antepartum monitoring), continuous electronic monitoring of Fetal Heart Rate and uterine contractions is indispensable since it gives a continuous flow of information enabling a very close supervision of the fetus.

5.2 "High-risk" pregnancies, in which antepartum monitoring has not detected signs of impaired fetal health, require less close attention. However, this group should be monitored throughout labor.

5.3 In "therapeutic induction" of labor, fetal monitoring is indispensable because (a) the induction is performed in a "high-risk pregnancy" which may have a "sick fetus"; (b) it is important to monitor the intensity, frequency and tone of uterine contractions, to adjust the dose of oxytocin necessary to promote the progress of labor without jeopardizing the fetus.

5.4 Advantages of intrapartum fetal monitoring. It is the most reliable method for making early diagnosis of fetal distress and applying the appropriate corrective measures before irreversible damage is produced to the fetus.

5.5 Disadvantages of intrapartum fetal monitoring. One inconvenience with the method presently employed for monitoring is that the parturient woman has to remain quiet, usually in bed, during labor. Several investigations have shown the advantages of having the mother moving freely as she wishes, standing, walking, sitting. The upright position is preferred by parturient women because they feel more comfortable and less pain is perceived than in the recumbent position. Telemetry systems will be most useful to transmit the signal from a parturient woman who is moving freely to the fetal monitor.

5.6 Several papers have been published (Haverkamp et al., Renou et al.) on "high-risk" pregnancies showing that with good clinical auscultation of the fetal heart rate, the results of labor management are as good as with electronic fetal monitoring and pH measurements in fetal blood. Such types of prospective randomized studies are excellent for giving us the proper value of fetal monitoring.

5.7 Fetal monitoring should not interfere with natural spontaneous labor. Membrane should not be ruptured with the purpose of inserting an electrode on the fetal scalp. Only if with non-invasive methods signs of alarm appear is it justified to rupture the membrane and insert a scalp electrode. If the tracing of FHR thus obtained confirms the diagnosis of fetal distress, blood sampling from the fetal scalp should then be obtained.

5.8 All these technologies are not incompatible with a home-like environment, where the parturient woman can receive the moral support of her husband and other members of the family.

5.9 Pain-relieving medication, sedatives and anesthesia should be used only when indispensable. The fully-awake mother should have an active participation and enjoy the event of having a child and start an early interaction with the neonate. These are some of the biological base of family unity and happiness.

Breast feeding should start as early as possible after birth, and the neonate should remain with its mother with as much and emotional and physical interaction as possible.

BIBLIOGRAPHY

1. Caldeyro-Barcia, R.: Estudio de la anoxia fetal intrauterine mediante el ECG fetal y el registro contínuo de la frecuencia cardíaca fetal. *III Congr Lat Am Obst et Ginec*, México, 2:388-390, 1958.

2. Caldeyro-Barcia, R. et al: Effects of uterine contractions on the heart rate of the human fetus. 4th International Conference on Medical Electronics, New York, 1961, p. 1.

3. Caldeyro-Barcia, R. et al: Effects of abnormal uterine contractions on a human fetus. *Mod Probl Pediatr*, 8:267-295, 1963.

4. Caldeyro-Barcia, R. et al: Control of human fetal heart rate during labor. In: *The Heart and Circulation in the Newborn and Infant*. D.E. Cassels, ed., Grune & Stratton Inc., New York, 1966, pp. 7-36.

5. Caldeyro-Barcia, R. et al: Effects of abnormal uterine contractions on fetal heart rate during labor. *V World Congr Gynaec Obstet*, Butterworths, Australia, 1967, Supplementary Main Papers, pp. 9-29.

6. Caldeyro-Barcia, R. et al: Correlation of intrapartum changes in fetal heart rate with fetal blood oxygen and acid base balance. In: *Diagnosis and treatment of fetal disorders*. K. Adamsons, ed., Springer-Verlag, New York, 1968, pp. 205-225.

7. Caldeyro-Barcia, R. et al: Diagnostic and prognostic significance of intrapartum fetal tachycardia and type II dips. In: *Prenatal Life*, H.C. Mack, ed., Wayne State Univ. Press, Detroit, Mich., 1969, pp. 129-153.

8. Caldeyro-Barcia, R. et al: A new approach to the treatment of acute intrapartum fetal distress. In: *Perinatal Factors Affecting Human Development*, Pan American Health Organization, Washington, D.C. 1969, Scientific Publ. No. 185, pp. 248-253.

9. Caldeyro-Barcia, R. et al: Fetal monitoring in labor. In: "Maternal and Child Health Practice: Problems, Resources and Methods of Delivery". Eds. Helen M. Wallace, Edwin M. Gold and Edward Lis. Publs. Charles C. Thomas (1973).

10. Freeman, R.K.: The use of the oxytocin challenge test for antepartum evaluation of uteroplacental respiratory function. *Am. J. Obstet. Gynecol*. 121:481-493, 1975.

11. Hon, E.H.: *An Atlas of Fetal Heart Rate Patterns*. New Haven, Conn., Harty Press, Inc. 1968.

12. Pose, S.V. et al: Test of fetal tolerance to induced uterine contractions for the diagnosis of chronic distress. In: *Perinatal Factors Affecting Human Development*. Pan Amer. Health Org. Scientific Publication, No. 185, 1969.

13. Rochard, F. et al: Non-stressed fetal heart rate monitoring in the antepartum period. *Am. J. Obstet. Gynecol.* 126:699-706, 1976.

14. Schifrin, B.S. et al: Contraction stress test for antepartum fetal evaluation. Obstet. Gynecol. 45:433-438, 1975.

15. Schifrin, B.S.: Antepartum fetal heart rate monitoring. In: Intrapartum Asphyxia and the Developing Brain. Ed. by L. Gluck. Yearbook Publishers, Chicago, 1977, pp. 205-224.

16. Schifrin, B.S.: Antepartum evaluation of fetal condition. Personal communication, 1978.

Senator **Kennedy**. Thank you very much, Doctor.

Thank you very much, members of the panel.

We have a final panel, representatives of the American College of Obstetricians and Gynecologists.

Dr. Ervin E. Nichols, M.D., director, practices activities, the American College of Ostetricians and Gynecologists; Richard Paul, M.D., Department of Obstetrics and Gynecology, University of Southern California at Los Angeles; George Ryan, M.D., Department of Obstetrics and Gynecology, Memphis, Tenn.; and Leonard Smith, M.D., private practitioner, Hyannisport, Mass.

STATEMENT OF ERVIN D. NICHOLS, M.D., DIRECTOR, PRACTICES ACTIVITIES, THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, ACCOMPANIED BY RICHARD PAUL, M.D., DEPARTMENT OF OBSTETRICS AND GYNECOLOGY, UNIVERSITY OF SOUTHERN CALIFORNIA AT LOS ANGELES; GEORGE RYAN, M.D., DEPARTMENT OF OBSTETRICS AND GYNECOLOGY, MEMPHIS, TENN.; AND LEONARD SMITH, M.D., PRIVATE PRACTITIONER, HYANNISPORT, MASS., A PANEL

Dr. **Nichols**. Mr. Chairman, I will make my comments very brief.

We have brought to you three specialists in obstetrics and gynecology. Dr. Paul, who has been intimately related with the whole story of fetal monitoring almost from its inception, and who is associate professor from the University of Southern California.

Dr. George Ryan, who is related to Public Health Activities in Massachusetts at Harvard University, and now is director of ambulatory care in Tennessee.

We also thought it would be appropriate, Mr. Chairman, to bring you a real doctor, and that is one who practices, and who sees the patients, and who has to tell you how it is out there, and with that I would like to just make one comment that we in the discipline of obstetrics are faced with the unique challenge.

It is anticipated, by expected mothers, that they will have normal outcome, and that their baby will have approximately 75 years of useful productive life.

Unfortunately, there are a few that are destined by unanticipated complications to have less than an optimum outcome.

It is our challenge to identfy those patients, and to correct that problem, in an attempt to incure the right of being well born.

Dr. Paul will go next.

Dr. **Paul**. I would like, Mr. Chairman, to offer some remarks, rather than read the testimony.

Senator **Kennedy**. We will include all of your testimony in the record.

Dr. **Paul**. Listening to some of the discussion, I would like to point out that we frequently hear the statement about the United States and its circumstances as it relates to perinatal mortality. Within the last 3 weeks, I had an opportunity to hear a gentleman from Sweden discuss mortality in that particular country, and he contrasted that interestingly with a number of our States who, in fact, had better mortality. In other words, we, in some of our States, have mortality that surpasses European countries, and data for that I would be happy to provide as I will for others.

Second, the collaborative study that has been referred to, I would like to point out two positive findings that came out of that investment. One was that by using auscultation, we talk about fetal monitoring in our attempt to identify this unique patient, that with auscultation practiced in some 25,000 deliveries, the conclusion drawn from that particular experience was that the diagnosis of fetal distress was not possible with that technique.

Another finding in that particular study by Lilien was that there were unanticipated problems. In fact, 1.5 deaths occurred in every 1,000 births that weighed over 2,500 grams. These are babies in which one would anticipate a normal outcome represented 84 deaths in 56,000 births——

Senator SCHWEIKER. Please repeat that. You are talking a little too fast.

Dr. PAUL. This study involved 56,000 women who delivered term-size infants, that is greater than 2,500 grams, which is 5½ pounds. During the process of labor in the particular study, there was 1.5 deaths occurring, which meant a total of 84 women lost their baby——

Senator SCHWEIKER. 1.5 per what?

Dr. PAUL. Per thousand. I am sorry. 1.5 per 1,000. That means there were 84 babies that died during labor. When they look back at this, they can identify only in half of the cases a causative factor.

In other words, they found an explainable factor in half of that group. It points out part of the problem. That is, we are looking for an infrequent occurrence of death, fortunately, but it presents this challenge to us to identify. In most cases, the incidence of babies dying during labor will be roughly 4 per 1,000. I would like to move to monitoring. I will limit it. I would like to point out that ultrasound that we have discussed at some length is utilized in two specifically different ways. One where we take and obtain a picture of the baby, much like X-ray, alternative to obtaining that picture is, in fact, X-ray with known risks and known problems.

Senator SCHWEIKER. X-ray, you say?

Dr. PAUL. Yes; ultrasound used in that fashion permits us to obtain many times better information. It is my personal judgment of the risk of ultrasound we do not know. That was one of the statements. I think personally the risks are outweighed by the benefits when one contrasts those two techniques. Fetal monitoring uses or employs at times ultrasonic methods. In our institution we use it in less than 10 percent of the patients that we monitor. There are other techniques. We can obtain heart rate using other techniques than ultrasound.

The things that I have personally seen and are a dramatic reduction in occurrence of deaths occurring during labor in women who are monitored, that is not saying monitoring is the only factor, it is saying with an interest in the fetus we have seen dramatic reduction occurring during labor. We have seen increased benefit to very-low-birth rate, infant survival, that has been monitored. We have not experienced dramatic change in cesarean section rates in our institution, which is sizable——

Senator SCHWEIKER. Your finding contradicts earlier testimony?

Dr. PAUL. I am saying in our institution, which delivers about 14,000 babies a year, which is from socially deprived group of patients, we have seen an increase, but it has not been a dramatic increase.

Yet we increased monitoring from 18 percent in 1970 to 48 percent in the past year.

We have seen dramatic increase in monitoring. We have not seen concurrent doubling, for instance of cesarean section rates——

Senator SCHWEIKER. Is that because your institution is more sophisticated in using that technique?

There is obviously a difference here.

Dr. PAUL. I attribute that to probably a number of factors, one being there is a number of individuals who have been intimately involved with the technique. It is a new technique which we are learning and we are teaching. By that method I think we probably preclude some of the problems that Dr. Haverkamp referred to, that we might out of a lack of information intervene perhaps unnecessarily.

Senator KENNEDY. Just on this point. As I understand it, one of the developers of the technique that left Yale is now with the university, am I correct?

Dr. PAUL. Yes, Dr. Horn.

Senator KENNEDY. You only deal with 48 percent?

Dr. PAUL. Currently we are using it in 48 percent of our patients.

Senator KENNEDY. Do you favor using it in 100 percent?

Dr. PAUL. Ideally, yes, I would prefer using it in 100 percent. I think when you get down to the 1-on-1 patient, that patient would be best served if I had all the information I could have and, therefore, I have to say, yes, I believe that is ideal.

Senator KENNEDY. Do you think it ought to be used in 100 percent of the hospitals in this country, knowing what the statistics are in terms of the growth of cesarean rates and the rest, you favor your position as 100 percent in the hospitals of this country?

Dr. PAUL. I said ideally used, it should be used in every patient and in all hospitals therefore. Now, the question is whether it is practical at this point in time and do we have the understanding?

Senator KENNEDY. That is a pretty basic question.

Dr. PAUL. That is a basic question.

Senator KENNEDY. You are prepared to say we ought to use it without knowing that evidently?

Dr. PAUL. I am saying in our hospital we do 48 percent.

Senator KENNEDY. I understand that. Let us be frank about it. I understand discretionary use in terms of your hospital, 48 percent. That is a lot different than a requirement that it be used in 100 percent. That is what we are talking about in terms of the parameters of this.

With all the implications that has, with the growth of cesarean sections and the rest, I am trying to find out what you know about it, whether your position is that you think it ought to be used in 100 percent of the births of this country.

Dr. PAUL. Ideally, yes.

Senator KENNEDY. What is ideally?

Dr. PAUL. That gets down to where I am taking care of the one patient, I understand the limitation of the technique, and I believe that the benefits for my patient outweigh the risks, benefits far outweigh the risks for that one patient. When you say should everybody use it in its current state of development, in the current application, I think then we have to say there are many people who do not have the expertise at the current level for various reasons.

This is a new tool. They have not had the opportunity to learn in their training process. Therefore, at the present time it would be inappropriate for those individuals to utilize the tool the same way as we would not let a 10-year old drive a car. It is an indirect answer. I have to separate it in my own mind, that my taking care of the individual patient and knowing what I know, I think she is better served by that technique. That is different than the practical question which you are asking, and that is should everybody at this moment in time have monitoring, considering our state of understanding.

That answer, I think, is probably no.

Senator KENNEDY. You say probably no?

Dr. PAUL. Considering the limitations of education that have gone on to this point, which are ever increasing, I think under those circumstances, to say to every patient you should have it would be inappropriate in a practical sense.

Senator JAVITS. Dr. Paul, may I ask one question.

To what extent is your opinion connected with the issue of malpractice, that is malpractice insurance, suits and so on?

Dr. PAUL. In our particular institution, we are a county hospital facility, and really I think we are not really swayed by that particular issue in our particular setting.

We do what we believe is best for our patient. We do not have that particular concern.

Senator JAVITS. Dr. Nichols, I have to leave. When you come to the question time, would you address yourself to that question and any recommendations you have?

Dr. NICHOLS. Shall I answer now, sir?

Senator JAVITS. With our chairman's permission.

Senator KENNEDY. Fine.

Dr. NICHOLS. We believe this is a very important consideration. My position as director of the college, well, I have the opportunity to review a number of professional liability cases. The problem in the patient who is delivered without a monitor in terms of liability, if there is a defective youngster, becomes a very major thing. And these suits, unfortunately, are the multimillion dollar suits. This is the thing that is really hitting the obstetrician. This is the thing detracting people from practicing obstetrics. Just one fact which I am sure the Senator knows. To buy professional liability insurance in Dr. Paul's State, California, where I am originally from, is now in the area of $25,000 to $35,000 before he can open his door, to protect himself against that. Therefore, the answer to that is it a very definite——

Senator JAVITS. Do you have any recommendation on this?

Dr. NICHOLS. In terms of monitoring?

Senator JAVITS. No. What to do about it.

Dr. NICHOLS. Of course, professional liability is a long and complicated one, but we do believe, as Dr. Paul has indicated, that any device or technique that we have that will further enhance and protect the patient is to the best interest of that patient. That is the whole purpose, to get the best possible result for the patient.

Senator JAVITS. You really favor ultrasound, assuming lots of things about it, because in addition to everything else, it is critically important to the practicing gynecologist in terms of insurance?

Dr. NICHOLS. I would like to separate ultrasound from monitoring.

Senator JAVITS. Monitoring, excuse me.

Dr. NICHOLS. Yes, sir.

Senator KENNEDY. The point is that you are justifying this procedure not on the basis of malpractice, you are basing it on sound medical judgments. I think there is an issue of malpractice but the fact of the matter is your documents—you are burgeoning it on the basis of medical procedure.

Dr. NICHOLS. That is correct.

Senator KENNEDY. Here we have had three different studies—Haverkamp study, the Weinberg study, and the Neutra study, related to high risk, which on first hand shows there is no effective difference in terms of types of monitoring that you are recommending and, second, we have various reviews and studies that have been done in FDA that raise serious questions about the long-term hazards of ultrasound.

What I am interested in is getting the response on those two issues. On the one hand, we hear studies which have been done, which I have not heard contradicted, show effectively there is no real kind of benefit from it in terms of the health, and there is very significant additional costs, and also additional cesarian sections. Even if you meet that, how do you respond to the serious questions that have been raised in report after report about long-term biological hazards of ultrasound and what kind of assurance you are able to give that this is a manageable problem?

I think that poses the issue you want to hear, whether you have more information, FDA, and these various studies, the three different studies that have been done, that ease the patient's mind.

Dr. NICHOLS. Can I refer this back to Dr. Paul, inasmuch as he probably has a larger set of statistics than anyone else in this country, I believe he should answer.

Dr. PAUL. I would like to look at ultrasound first because that is something that is used, a technique, I said, in our particular institution we use that probably in less than 10 percent of the patients that we monitor electronically.

Senator KENNEDY. Why is that?

Dr. PAUL. We grew up in using direct techniques, we take the electrocardiogram from the baby during labor as opposed to using external technique, and so my experience is based primarily on that particular technique. There are times unequivocably when external monitoring has to be used, and I can show—again it is anecdotal, case after case, where by using this we identify a problem we would have been otherwise unaware of, and we have acted in what we think is in the best judgment of that particular fetus.

So I think ultrasound provides a tool which gives us information which we employ in, I think, a reasonable way. That is ultrasonic thing. When we move to the problem of how or whether we define whether something is beneficial or nonbeneficial, I refer to the incidence of occurrence of deaths during labor, which is around 4 per 1,000.

If we take and idealize that and can have one nurse standing with one patient, and that is what Dr. Haverkamp did, we might improve on that particular incidence of occurrence. His study, the first one was 400 patients, how many deaths would you suspect in that group—he had none. The question is, I have looked back at our experience which is 30,000 patients that have been monitored, and they have been monitored because they have problems. I can show you that they have an outcome that is equally as good as babies who have the standard approach.

That is indirect retrospectively gained experience.

There is study after study that says the incidence of occurrence of death in labor, babies, diminishes dramatically with the awareness of the fetus and with concern in monitoring. It will go, for instance, from 5 per 1,000 down to less than 1 per 1,000.

If you translate into a hospital, it does 4,000 births a year, that means you may have 4 babies unexpectedly die instead of having 20.

But the other question is, what about babies that do not die? Are we preventing in the process damage that is well-known problem to all of us, that we try our best to avoid?

Senator **Schweiker**. Dr. Paul, I would like to come back to that point. You made a statement earlier that I do not understand the significance of. You said that the Lilien study showed 1.5 deaths per 1,000.

Dr. **Paul**. I am giving incidence of occurrence. This is collaborative study, 56,000 babies were studied in that group, 84 of those babies died during labor.

Senator **Schweiker**. What about the 4 per 1,000?

Dr. **Paul**. I think ultrasound provides a tool; 56,000 babies were studied in that group.

Senator **Schweiker**. Right.

Dr. **Paul**. Eighty-four of those babies died during labor.

Senator **Schweiker**. At a rate of 1.5 per 1,000?

Dr. **Paul**. That is the rate of 1.5 per 1,000, so we are looking for the needle in the haystack.

Senator **Schweiker**. But I thought you said a moment ago that 4 per 1,000 was the norm.

Dr. **Paul**. I am sorry. Those were babies that weighed over 5½ pounds. In other words, those were babies that, by every right, you would expect to survive; 1.5 per 1,000 of those babies died during labor.

Now, the overall number, if you take babies that weigh less than that, is 4 to 5 per 1,000 in most recorded series.

Senator **Schweiker**. But is there any direct linkage between those figures and the figures that would occur if you used ultrasound?

Dr. **Paul**. Well, I think maybe I could say if you used monitoring. I could show you data from many places where the incidence of death during labor is less than 1 per 1,000. Some people claim to have totally eliminated it, but their numbers are not large.

In our institution, the number is less than 1 death per 1,000, so it has been dramatically decreased, with the limited application that we, in fact, have used.

Senator **Schweiker**. So the 4 per 1,000 is based on a norm of treating——

Dr. **Paul**. All babies.

Senator **Schweiker**. And the 1.5 per 1,000?

Dr. **Paul**. It is term-sized babies, and that was the collaborative study that documented that.

Senator **Kennedy**. Dr. Nichols, given the studies that you reviewed earlier, the FDA studies, do you still agree with the statement of policy that this diagnostic service we are talking about, ultrasonic service, should be available to all prospective patients?

Dr. **Nichols**. Yes, sir.

Senator **Kennedy**. The danger to the fetus or mother from external monitoring are only theoretical?

Dr. **Nichols**. That is correct, sir.

Senator **Kennedy**. Only theoretical?

Dr. **Nichols**. To our knowledge, yes.

Senator **Kennedy**. What information do you have, balanced against the other kinds of studies, that that is only theoretical? If you have scientific information, we ought to get it over to the Commissioner of FDA, because he certainly does not agree with that.

Dr. **Nichols**. Well, let me say first that the availability of ultrasound—and this is what we are talking about, is availability in an institution so that it is there if needed—and, again, I am concerned that the committee has confused diagnostic ultrasound against fetal monitoring ultrasound. They are entirely different situations.

In terms of the ultrasound availability, that is what we are talking about, so that if you want to look at the whole baby inside, you can take a picture of that baby; that is what the document is referring to.

Now, in terms of the other——

Senator **Kennedy**. Doctor, let me understand you. You are not suggesting that it should go to every single patient?

Dr. **Nichols**. That is not the context of that statement; no, sir.

Senator **Kennedy**. You also point out that external monitoring has only theoretical problems; there is no evidence to suggest that ultrasound is deleterious to the fetus. Usually, we require things to be shown safe, rather than to be shown the other side.

Dr. **Nichols**. Well, unfortunately, there is no way that I am aware of—and this is where the Food and Drug Administration is in severe difficulty with this; I happen to be on one of those committees and I hear the discussion—it is extremely difficult to monitor, say, 1,000 or 10,000 patients without doing it. You cannot use animal studies at this particular time; it just does not translate.

Over the hundreds of thousands that have been monitored at this point, we are unaware of any evidence of sustained damage to the fetus.

Senator **Kennedy**. That is up to this point.

Dr. **Nichols**. Yes, sir.

Senator **Kennedy**. You are very much aware that there have not been reviews over a longer term, monitoring what the impact has been on the fetus. You do recognize that?

Dr. **Nichols**. Yes, sir.

Senator **Kennedy**. And is that troublesome or bothersome to you at all?

Dr. NICHOLS. Well, what is the alternative? In other words, if it is the removal of the device, then we have another problem. When we are talking about the cost benefit or the risk benefit, it is our opinion that the risk benefit is to the patient's advantage.

Senator KENNEDY. Dr. Haverkamp's study and the Neutra study would indicate that in terms of looking at that risk benefit, they draw different conclusions.

Dr. NICHOLS. I understand that, sir. As I recall their studies, they were on very small numbers, and Dr. Paul has just given you rather large numbers which tend to——

Senator KENNEDY. If you want to have your people do an analysis of the basis of those studies—I inquired before our hearing, in terms of the staff going through those, whether they had been contradicted or whether there was an analysis of them, the conclusion of which was that they were nonscientific or not accurate. I had not heard that that was the case. I think we would refer those to you and ask that if you have other information on that, that you provide it.

Let me ask this question: Dr. Paul, in the examples he gave, indicated that cesarean sections had not increased significantly or dramatically. The other studies that I have mentioned here would show that there is a dramatic, three- to four-fold increase in terms of cesarean sections. Would that be of concern to you?

Dr. NICHOLS. That is very much of a concern of the college, and I would refute that particular number. We have been watching the numbers across the Nation fairly well, and I think that we are somewhere in the neighborhood of 12 percent; 12 to 14 percent is probaby the average across the country.

Senator KENNEDY. What we are talking about is where there has been a lot of monitoring; not just generally across the country, but where there is a monitoring of the fetus, and a dramatic increase in terms of cesarean sections. Those were the basic kinds of conclusions in those studies.

Dr. NICHOLS. Well, I would agree, Senator, that in some of those areas, we do have to take a look at that. We do not have the hard data on that to associate the increased section rate with the monitoring, and that is a study that has to be done.

Senator SCHWEIKER. Just following up that point, Dr. Nichols, do you concur with the figures that we have presented here to use that the 11 or 12 percent we are at now—you said 12 percent was probably a cross-section figure—that that has almost doubled since 1972. In other words, we have figures in front of us that indicate that that is a doubling of what the rate was 6 or 7 years ago. Do you concur with that?

Dr. NICHOLS. I surely do, and let me just add to that, that in the last two decades, particularly the last 10 or 15 years, the whole science of obstetrics has changed. We have taken our emphasis away from the health of the mother, if you will, inasmuch as we have come to the epitomy, we think, in terms of preserving her situation, but we have now moved our attention to the fetus.

What we can surely show you, with the increased section rate, is a very definite increase, or a lessening, if you will, of perinatal mortality and the lessening of perinatal morbidity. And this becomes very cost-effective, Senator.

Senator SCHWEIKER. So you are not concerned about that trend, then?

Dr. NICHOLS. That 12 percent, no, sir.

Senator SCHWEIKER. Would you say it is a beneficial trend?

Dr. NICHOLS. I surely do, yes, sir.

Senator KENNEDY. Dr. Ryan?

Dr. RYAN. I will abstract the testimony that you have there. I would first like to say that I will not review the perinatal and maternal figures. But, as I have mentioned on page 2, I have included the figures from the last decade for you, so that you might see that the perinatal mortality rate has dropped 25 percent over the last 10 years.

In contrast to the figures from way back in 1930, this does not represent the introduction of antibiotics or blood transfusions, or a host of other basic improvements. Instead, the last decade represents changes in the practice of perinatal medicine, including the delineation of risks earlier in the prenatal course, more intensive care for the high-risk patient, the ability to evaluate the fetus before delivery, the ability to intervene on behalf of the fetus if the fetus is in danger, and newborn intensive care for the infant who is born seriously ill.

In spite of these statistics showing improved outcome of pregnancy, physicians, and others, have insisted that we continue to examine and reexamine the effects of our current practices, and to try to assess the risk-benefit ratio of these practices As scientists, we welcome these inquiries and, indeed, our scientific literature is filled with reports of studies to try to answer some of these questions.

I am disturbed by the tendency of some individuals, both within and without the profession, to conclude that they know the answer, and to insist that others within the profession be forced to practice according to their views.

Elective induction of labor is one such discussion point that has gone on for many years. Back when I was a resident in the 1950's, it was generally considered hazardous. We had an extract from animals, pituitrin, which was used. We did not have synthetic oxytocins.

In the 1960's, these became available. With their continuing widespread use and our experience with them, there were several studies attempting to answer the questions. I have mentioned the studies of the National Birthday Trust in Britain, which showed that induction, at term, over a broad population presented, at that time, about a 30-percent improvement in perinatal mortality.

Over the past decade, we have had increasingly sophisticated studies; studies from blood gases (oxygen and carbon dioxide), the pH changes in the infant—sophisticated capabilities—which began to, again, raise the question of the wisdom of elective induction.

However, if those people who question it think they have the answer, it would seem unwise, since, indeed, there are still papers coming out from clinical studies on patients indicating the safety and efficacy of elective induction.

Again, let me point out that I am not here to tell you that elective induction is great. I think the major disadvantages are, very clearly, the possibility that we may deliver a premature child, and there are other hazards which we are now able to measure in the changes in the baby's physiology.

However, there are some advantages. There is, indeed, a psychologically positive attitude in some mothers who have a firm date as to when their babies are to be born. I need only to give you the illustration that we have many people who travel considerably in this country.

A women who is likely to be separated from her husband because of a trip he cannot avoid and who wishes to have him with her in labor and delivery, which concept we support, might, indeed, wish to have that baby planned at a time when her husband will be home. So, there are occasions when we think it is positive.

A labor continuously supervised, from start to finish, we think is important. A certain number of infants will be lost in the early stages of labor if the patient has that labor at home, outside the hospital, with no supervision, and waits until she is halfway through before she arrives at the hospital. A certain number of cords will pull tight around the neck; a certain number of knots will pull tight in the cord.

A certain number of placentas will separate. We will lose some babies. We do not lose those babies with the patient in the hospital being carefully monitored by whatever method you may choose.

I think, in summary, the physiologic findings which, indeed, cause us some concern are not always translatable into the outcome of pregnancy. The risk/benefit ratio for elective induction of labor is as yet unanswered.

As to increasing cesarean section rates in the United States, there have been many reviews recently. In summary, most of the recent studies seem to indicate an increased incidence of cesarean section, but only a small portion of this increase is related to the use of monitoring and the identification of fetal distress.

It has been my impression that many of the charges from outside the profession—there is a typographical error there; "charges" instead of "changes"—related to the increasing cesarean section rate and its relationship to monitoring have come from those individuals who oppose the use of monitoring and have seized upon the increasing cesarean section rate as a means of discrediting it. This is, in my opinion, a gross distortion of fact.

The fact is, by all of our studies, that knowledge which has become available in recent years has led us to question some of the practice patterns of the past which produced infant damage from long, difficult labors, traumatic forceps deliveries, and difficult manipulation of the fetus at delivery.

This knowledge and the resulting changes in practice patterns have allowed us to continue to improve the perinatal outcome in the United States today. The increasing incidence of cesarean section thus represents a step forward from the days when the excellence of a service was judged by how low they could maintain that rate.

Some small part of the current increase is certainly due to the use of monitoring, and this is as it should be. Monitoring allows us, for the first time, to recognize early signs of fetal distress before the baby is permanently damaged. If vaginal delivery is not feasible, the only other form of intervention is cesarean section. Not to act in this way in a situation in which the fetus is in jeopardy would be the utmost in therapeutic nihilism.

Again, we thank you for the opportunity to address the committee today.

Senator **Kennedy**. Thank you. I would think, Dr. Ryan, we ought to know what the facts and statistics are. If we have an important increase in cesarean section as a result of monitoring, we ought to lay that out and tell what that percent is, and be able to evaluate it in terms of what the increased kinds of risks versus the benefits are. We should balance that against what the studies have been in terms of the ultrasonic monitoring, as well, where we have got the statistics and information showing that the benefit has not been demonstrated.

I think it is important that these kinds of figures and statisics be laid out on the table, so that we have a basis to make a comparison. We found in Dr. Paul's examples about cesarean section had not increased. A number of other studies show that there is a significant increase in cesarean section. We ought to just find out what the statistical basis for that is.

I think it does not make much sense to have generalizations about these, trying to discredit each other's positions on it, but to try and find out what the real health benefits are going to be in terms of this technology and what the benefits are going to be to the fetus and to the mother; what the costs are going to be; what the attendant side effects are going to be.

I suppose if we had had obstetricians and gynecologists here 15 years ago, they might have been here suggesting that we use DES; that they have used DES individually for 8 or 10 years and found that it had very constructive results. Only 15 years later, we find out about the attendant problems. I suppose we would find out the same kind of thing with Premarin, used for 30 years before we found out about these problems.

Now we have on the horizon various groups that have considered ultrasound raising the issues of biological hazards on three or four different studies on it. We hear Dr. Nichols say that we cannot say, with any degree of assurance over the longer period of time, what the biological impact would be in terms of these. We do not know what it is today and the FDA is in a dilemma of being able to project or predict down the road.

It seems to us that in this specialty, we would advise a good deal of caution in terms of these new kinds of technologies and devices, because we cannot show the health benefits involved.

Dr. **Ryan**. Senator, certainly we are concerned, as you are. Those might be generalizations that I stated, because I abstracted considerably from the material I had to present. But I would point out to you that there are several studies indicating a reduction of loss of the baby during labor from an area of 3 to 5 per 1,000, overall, down to below 1 per 1,000.

Now, we think that is a definite benefit, and if we have that clear a benefit from the monitoring process during labor, and we have an unrecognized risk, one which is unknown, certainly it is very difficult to avoid facing up to the fact that we have a definite benefit staring us in the face.

Senator **Kennedy**. Well, that is obviously enormously important, and we ought to have the bottom line. There are those who have done extensive studies—creditable individuals—studies that have not been, at least that I have seen, tested on the basis of scientific information. They reach one result.

I do not know what the basis of yours is. Is this your own study?

Dr. RYAN. No, sir, we would be happy to send you the statistics. We have reports in the literature. Everybody pulls the reports that support their position, I suppose, and we are probably no better than others at that, but we do have reports that are quite as impressive as the figures you have heard maligning the practice.

Senator KENNEDY. We ought to have them and we want them submitted. There ought to be at least scientifically sound information on this, on which a judgment can be made.

Just as a final point, in summarizing your testimony, I hope that there would be a better kind of example than the convenience or a trip or the length of a trip, as to the potential danger or harm to the fetus or the mother. There must be other kinds of benefits that would prove the testimony. I hope you do not mind if I remain a little unpersuaded by that argument.

Dr. RYAN. No; I simply meant to imply that patients truly bring a great deal of pressure on their physicians for their own reasons, and the physicians are serving individual patients. In that process, it is sometimes difficult to withstand that kind of pressure. Without clear evidence that you are creating a risk-taking situation, then the physician may succumb to that kind of pressure.

Senator SCHWEIKER. Dr. Ryan, I certainly concur with you on the figures that show a decline in morbidity and mortality among infants. I think they are very significant. We have made some progress in health education—at least in prevention—and also better prenatal efforts, such as nutrition, identification of risk factors, alcohol, drugs, and smoking. That has to be part of this, too. How do you relate one to the other?

Dr. RYAN. Well, as indicated, we have reexamined a great deal of our practices. For instance, in that study which was somewhat maligned earlier this morning, one of the great important parts of that study was the identification of the breech delivery, which occurs in approximately 4 percent of the population, as being one of the major causes of fetal injury related to birth.

Now, it identified it very clearly and we have been able to act upon that. In the succeeding decade, we have approached breeches with much more caution. In fact, breeches are one of the major reasons for the increase in cesarean sections. When you take the increased incidence of cesarean section—again, as I said earlier, fetal distress as a diagnosis relates to only about 20 percent of that increase—80 percent of that increase is due to the marked changes in our practice.

Now, we cannot say the improvement is due to any one thing, but we do believe that the improvement is a combination of all of these things—better handling of the breeches, less traumatic forceps deliveries, reduced injury to the babies simply because we are approaching them in a different way, and it has been based on that $150 million study.

Senator SCHWEIKER. Thank you.

Dr. Smith?

Dr. Smith. Thank you, Senator. I am a practicing obstetrician in Hyannis and have been practicing there for 14 years. I am chairman of the department of OB–GYN at the Cape Cod Hospital, and I am the chairman-elect of the Massachusetts section of the American College of Obstetricians and Gynecologists.

The practice of obstetrics has changed dramatically since my beginning in Hyannis 14 years ago. Initially, we as obstetricians were concerned with having a live mother and a live baby as a successful outcome of pregnancy care. With the dramatic improvement in maternal and fetal mortality, we are becoming considerably more concerned about the quality of life for which we are responsible, for we as obstetricians are, in the labor and delivery suite, responsible for two lives, with respective life expectancies of 70 years for the infant and 30 to 35 years for the mother.

With the excellent and dramatic improvements in the mortality rates, we now have the more extensive concern to insure that mother and child are not only alive, but healthy.

Fourteen years ago, I had very little idea of the status of the infant in labor, except for the transitory, every 15-minute auscultation of the baby's heartbeat, with the stethoscope. With the aid of the monitor, I can now know what the every-minute status of this infant is. I can know whether the stress of labor is or is not affecting the child.

In my own practice, I have found very little patient objection to the use of the monitor. To the contrary; it has proven in most instances to be reassuring not only to the obstetrician, but also to the patient herself, for she can see visually that the baby's heart rate is doing well.

The most frequent question asked by both expectant mothers and fathers is, "Is everything going OK?" Now they can see for themselves. In addition, the monitor can aid us in determining the rate and efficacy of the patient's labor contractions, and it is one of our tools in determining whether oxytocin augmentation is necessary to increase the effectiveness of uterine contractions.

There is a place for oxytocin in an instance such as this when the uterus is not contracting properly. There is an additional use for oxytocin in induction for many medical reasons, such as diabetes, Rh problems, hypertension, premature ruptured membranes, et cetera.

There are other indications for oxytocin induction which are not related to a specific disease entity, and I consider a good example of this to be the patient who lives in Provincetown, some 55 minutes away from the Cape Cod Hospital and she delivered her last baby within an hour of labor.

A striking change in the delivery of care in obstetrics has been the change in approach to cesarean section. Fourteen years ago, most obstetrical services, including my own took pride in keeping the cesarean section rate per 100 deliveries as low as possible. Again, our aim at that time was primarily a live baby.

This concept necessitated traumatic. difficult forcep deliveries; prolonged, arduous labors; and birth injuries to both mother and child. Today, gone are the traumatic forcep deliveries; gone are most of the anxieties of delivering breach babies and watching them have great difficulty breathing, or with severe injury; gone are the 24- or 30-hour-long labors endured by many exhausted mothers-to-be.

I am sure that concern exists about the cost increase in the rise of cesarean sections, and I can agree with that concern. But I would like to briefly mention two studies as they relate to breach deliveries.

In Sweden, a retrospective study was done comparing schoolchildren who were born in breach presentation, versus those born in vertex or head-first presentation. The breach delivery group had essentially twice as many difficulties with reading and writing, with visual and auditory problems, and with speech disorders than did the vertex delivery group.

In New York City, a retrospective study showed the perinatal mortality rate to be three times higher in breach delivery, and the the traumatic morbidity rate to be similarly three times greater.

My point with these studies is to point out that a child with physical and intellectual disabilities will equally represent a cost increase in attempting to rehabilitate the child, and in the long run it may be far more cost effective to have the rising cesarean section rates, not to mention what it could mean to the child as an individual.

In summary, like any husband and expectant father, I was always extremely concerned when my wife was in labor with our children. I would be far less concerned today. The present-day care of pregnant women has, in my opinion, greatly improved over even 10 years ago, and I am sure that in 1988, we will look back on today and be able to say the same thing about 1988.

It is very possible that what we consider to be good obstetrical practice today may prove to be outdated then, because medicine, thank God, marches on. We obstetricians are continually trying to improve not only the mortality rate, but the quality rates, by audits, by ongoing comparative studies, by long-term retrospective evaluations, by research, et cetera.

Our basic concept has been, and will continue to be that every child has the right to be well born. Thank you very much, Senator.

Senator KENNEDY. Thank you for that fine statement. Do you monitor every patient?

Dr. SMITH. Almost every one, sir.

Senator KENNEDY. Do you think they all should be monitored?

Dr. SMITH. In my hospital, yes, I do.

Senator KENNEDY. Ultrasound?

Dr. SMITH. By ultrasound, yes. Almost every physician who is responsible for a pregnant patient in my hospital has had rather vigorous training in ultrasound and I think we are all convinced that this is beneficial for the baby and the mother in the long run.

Senator KENNEDY. Are you concerned, though, about the long-term safety effects in terms of that device?

Dr. SMITH. Yes; I am, but I am also concerned about the long-term effects of babies who are having distress in the uterus and we are not able to pick it up with other means. The presentation that Dr. Haverkamp had earlier was a one-on-one basis with nurses. That is a very nice, ideal situation, but it is a terribly expensive proposition to have every pregnant, in-labor patient have a trained nurse to be able to pick up fetal distress at a moment's notice.

Senator KENNEDY. When you take the results of the Cape Cod Hospital, which are different from the results of the Beth Israel Hospital where they did a very extensive study, or Dr. Haverkamp's studies out in Denver, why are they individually getting different statistical base for that information?

Dr. **Smith**. I am not sure my statistics are valid, because, after all, we are not delivering 13,000 or 14,000 babies a year, like Dr. Paul's hospital. I feel that in my relationship with the pregnant patient and her family, my responsibility is to have everything that I can possibly have to insure the heaalth of both her and the infant, and I feel that the monitor is a vital aid in doing that.

Senator **Kennedy**. Still, you are not troubled by the various kinds of studies that have been done with the long-term biological and cellular impact that may very well be a danger to the fetus?

Dr. **Smith**. I have to rely on Dr. Paul's authority on that, rather than my own. To the best of my reading and listening, the majority of tests, as of 1978, are not indicative of the few tests or reports that you have quoted. The majority show, so far, no evidence of a problem. As I said earlier, 10 years from now, things are certainly going to be different in the practice of obstetrics.

Senator **Kennedy**. The tragedy would be if, 10 years from now, we found out that there were side effects and we did not either anticipate or know, at the time the decision was made to use a particular device, the question about its importance in general terms.

As I mentioned earlier, one of the important studies shows important positive health implications in the areas of high risk. The other three studies show that the effective health benefits are not demonstrated.

I would just say, in conclusion, what I am impressed about is both your desire and the desire of the other witnesses to get to the bottom, in terms of the statistical facts so that sound practices can be developed. You are quoting your statistics and there are other studies showing others which reach different results.

I think part of the importance is that we get those who have done the studies—Dr. Nichols, your review and the basis for your judgment, together with those who have done the other studies—have them sit down across the table and review those and find out what the basis of these studies are and what conclusions may be drawn. That would seem to me to be an important requirement.

Dr. **Nichols**. May I say that I appreciate the comments, and may I say that progress in medicine is a continuum. This is how we make progress and we are certainly in agreement with your comments, sir.

Senator **Kennedy**. We will endeavor to try and establish that mechanism so that that information can be made available. The FDA has important responsibilities in approving medical devices, and our new institute which, hopefully, will review cost assessment of new technology will be able to provide that information.

I have no further questions. Senator Schweiker?

Senator **Schweiker**. Dr. Smith, as a practicing obstetrician, how often do you electively induce labor?

Dr. **Smith**. Very rarely. If there is not a medical reason—and I personally consider the example that I gave as a medical reason, to a certain extent—I do not.

Senator **Schweiker**. I realize if you make a decision in the middle of a delivery, that is one thing, but is there any standard procedure in terms of your practice in inducing childbirth?

Dr. **Smith**. Well, as I said, Senator, unless there is a medical reason for induction, I do not do it.

Senator **Schweiker**. Well, then I gather from what you are saying that if there is a medical reason, you would opt to make that judgment?

Dr. **Smith**. Well, I would explain to the patient the reasons why I felt that this infant was better outside the uterus than in the uterus and explain the procedure that is going to happen, and go from there, with a monitor to see how the status of the fetus is doing at the same time.

Senator **Schweiker**. Thank you.

Senator **Kennedy**. Dr. Nichols, you have got some studies that you are going to provide, are you?

Dr. **Nichols**. I am going to try, sir; I am going to try to make the committee happy.

Senator **Kennedy**. Well, we want to be more than happy. We want to be informed; I guess that would be better.

Dr. **Nichols**. Yes, sir.

Senator **Kennedy**. We would appreciate it. We want to thank you very much. Thanks for coming.

[The prepared statement of Dr. Nichols and additional material supplied for the record follows:]

TESTIMONY OF

THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

on

CURRENT OBSTETRICAL PRACTICES IN THE UNITED STATES

before the

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

COMMITTEE ON HUMAN RESOURCES

UNITED STATES SENATE

April 17, 1978

I am Ervin E. Nichols, Director of Practice Activities of The American College of Obstetricians and Gynecologists, which represents over 20,000 physician specialists and 18,000 nurses in the discipline of obstetrics and gynecology. I spent 20 years in the practice of this speciality prior to joining the ACOG staff. During part of this time I served as Chairman of the Department of Obstetrics and Gynecology at Loma Linda University Medical School. From the time of my entrance into this discipline in 1946 to the present time there have been many changes in the delivery of obstetric care. In 1946 the maternal mortality was 156.7 per 100,000 live births, and the perinatal mortality was 34.7per 1,000. An acceptable cesarean section rate at that time was something under 5%.

In the past 30 years many changes have taken place. The maternal mortality rate has dropped to 12.3 per 100,000 live births. Another great stride was made when the obstetrician began to focus attention on the fetus in utero, which caused a remarkable drop in the infant mortality rate. This has created an entirely new type of speciality and that is a physician with special expertise on the fetus.

Today we have three experts who will present a summary which will relate to the questions presented to us by your committee.

Dr. Richard Paul has spent his total career involved in the development and implementation of techniques used in the assessment of the fetus both antepartum and intrapartum. His experience and information relate to a study which involves the largest number of monitored patients in this country. He is an Associate Professor of Obstetrics and Gynecology, University of Southern California.

Dr. George Ryan, with a degree in public health, is currently directing a major ambulatory care program in the State of Tennessee. Dr. Ryan recently moved from Boston and Harvard University to develop a coordinated regional program of obstetrical care founded on the public health system. Dr. Ryan was intimately involved in the preparation of the document, "Toward Improving the Outcome of Pregnancy" which has been referred to in the new Health, Education, and Welfare regulations as guidelines in the implementation of the health planning law 93-641.

Dr. Ryan is Professor of Obstetrics and Gynecology and Professor of Community Medicine -- University of Tennessee.

Dr. Leonard Smith will give final dimension to the equation, that is, how do the practicing specialists--the bulk of the providers--react to the evolving science of perinatal medicine and how do they implement this knowledge? Dr. Smith typifies the practicing specialist outside of the very large urban area and faces all of the situations encompassed in obstetric care. Dr. Smith practices in Hyannis, Massachusetts.

The speakers will follow one another in order as given. Following Dr. Smith's comments we will be pleased to answer any questions.

Dr. Paul
Page 1

Electronic fetal monitoring techniques were introduced and became widely accepted in obstetrical care during the 1970's. I have had the opportunity to be associated with the basic investigations beginning in 1961 and the subsequent introduction of these techniques into clinical usage.

My first experiences with clinical fetal monitoring occurred in 1968 when this type of instrument became available at Yale New Haven Hospital. The selective use of this tool led to a 75 % reduction in cesarean sections done for "fetal distress".

Since 1969 I have had the opportunity to work at the Los Angeles County/University of Southern California Medical Center. The Women's Hospital delivers one in every 225 babies delivered yearly in the United States (13,000-1[illegible],000 births). Monitoring was introduced in the fall of 1969. The incidence of monitoring in 1970 was 18% and has risen to 48% in 1977.

We have seen a halving of perinatal mortality over these years and I believe fetal monitoring has been an important factor in this benefit.

The occurrence of death during labor has decreased dramatically. The survival of very premature infants is significantly better when they have been monitored during labor.

The incidence of cesarean section in our hospital has not risen over the past 7 or 8 years even though the incidence of monitoring has more than doubled. Cesarean sections done for fetal distress have decreased with the ability to better interpret fetal condition as seen through the fetal heart rate.

The comment is frequently made that cesarean section deliveries are increasing as a result of monitoring. My general observation and opinion is that such a result, although probably transitory, could be anticipated. The introduction of this new diagnostic tool may cause a degree of legitimate obstetrical concern and honest confusion. This trend will change as educational approaches improve and understanding is developed.

The aspect of drug usage during labor is inherently intertwined with fetal monitoring. The fetal response to medications may be rapidly seen in the fetal heart rate. The absolute significance of such findings is unclear at this time. The trend in my hospital and across the country is toward the lesser use of analgesic drugs and a more natural birth due in part to fetal monitoring.

In cases where anesthesia or drugs must be used, fetal monitoring is an invaluable tool. The first signs of an adverse reaction in the mother may be reflected by the fetal heart rate. Corrective measures may then be instituted to benefit both mother and fetus.

Fetal monitoring provides a means of positive communication regarding fetal well being. The fetus has become a specific patient for which the obstetrician has accepted the responsibility. Intrapartum monitoring, in my opinion, benefits both mother and fetus.

I am Dr. George Ryan. I am a Professor of Obstetrics and Gynecology and a Professor of Community Medicine at the University of Tennessee Center for the Health Sciences. I will address myself to the elective induction of labor and to current rates of cesarean section. First, however, I must make a few general observations. Obstetricians and gynecologists have three goals in the delivery of obstetrical care: 1) To protect the mother's health; 2) to produce a healthy baby; and 3) to make it as pleasant and emotionally gratifying an experience as possible for their patients. While there is rarely any conflict between the action needed to protect the mother's health and to produce a healthy baby, either one of these goals may create a necessity for actions that interfere with the goal of making it as pleasant as possible an experience for the patient. For example, it is not pleasant to receive an injection, yet the development of the technology of immunization has made it necessary for us to undergo this experience at times. Numerous other illustrations could be given, but I believe the point is clear. Actions important to the protection of the health of mother or baby may not always be pleasant experiences.

The combined efforts of medical personnel, including the obstetrician and gynecologist, have produced changes in mortality rates for mothers and their babies over the past decades, dramatically demonstrating the increasing ability to protect the mother's and infant's health. Maternal mortality was more than 600 per 100,000 live births in 1930 and had shrunk to 14.6 deaths per 100,000 births in 1974. Infant mortality was 64 per 1,000 in 1930 and had decreased to 16.1 per 1,000 in 1975. In other words, the maternal mortality rate is approximately one-fortieth of what it was in 1930 and the infant mortality rate is about one-fourth of what it was. The combined losses of infants before, during and after delivery is called perinatal mortality, and this figure was 47.2 per 1,000 live births in 1945 and had decreased to 33.7 per 1,000 in 1964, and reached 25.2 per 1,000 in 1973. (These are all United States figures.) Perinatal mortality is usually what we consider to be a measure of our effectiveness at the present time. I have included the figures from the last decade so that we might see that the perinatal mortality rate has dropped 25% over the last 10 years. Unlike the figures since 1930, this does not represent the introduction of antibiotics, blood transfusions, or a host of other basic improvements in medicine that have occurred. Instead, the last decade represents changes in the practice of perinatal medicine including the delineation of risks earlier in the prenatal course, more intensive care for the high risk patient, the ability to evaluate the fetus before delivery, the ability to intervene on behalf of the fetus if the fetus is in danger, and newborn intensive care for the infant who is born seriously ill.

In spite of these statistics showing continuing improved outcome of pregnancy, physicians and others have insisted that we continue to investigate the effects of our current practices and to try to assess the risk/benefit ratio of these practices. As scientists, we welcome these inquiries, and, indeed, our scientific literature is filled with reports of studies to answer some of these questions.

I am disturbed, however, by the tendency of some individuals both within and without the profession to conclude that they know the answer and to insist that others within the profession be forced to practice according to their views.

Elective induction of labor is one such discussion point that has gone on for many years. In the 1950's, when I was a resident, the generally held opinion was that elective induction of labor was potentially hazardous, and it was generally frowned upon by my professors. In the 1960's, the availability of oxytocins decreased the likelihood of failed induction of labor, and many physicians began to believe that elective induction was quite safe if one was certain that the infant was at or near term and therefore would not be a premature birth. In two major studies in Great Britain by the National Birthday Trust in which induction was done on a large population routinely at term, each showed approximately a 30% improvement in perinatal mortality in the induced labor group. This was taken to mean that, while induction might have hazards, it also had benefits in that it prevented some late pregnancy losses that would have occurred had the fetus remained in the uterus.

Over the past decade, increasingly sophisticated studies, including the capability of measuring blood gases in both mother and infant and the capability of monitoring pH changes in the infant, allowed us to make much more careful studies of the differences in impact on the fetus from induced labor and spontaneous labor. These studies have again raised the question of the wisdom of elective induction of labor. However, those who think the question has been answered because of a study that supports their point of view that this is an unwise procedure, must face the fact that there are other publications supporting the safety and efficacy of elective induction. One such study recently reported from Germany by Bolte and Breuker compared 601 elective inductions, 92 inductions of high risk pregnancies for a specific reason, and 1,829 spontaneous births. Without going into all of the data, suffice it to say that the birth weights of the newborns showed no significant differences in the three groups; there were no perinatal deaths, and no special pediatric treatment was needed in the induced labor babies. In the others, eight babies required long-term care, three from the high risk group and five from the spontaneous labor group. Again, let me point out that I do not present this as proof of the efficacy of induction, but simply to indicate there are studies still going on to evaluate the results in actual practice and not all are negative studies. The major disadvantage of induction clearly is that an error can be made and a labor induced before the baby has reached term. This subjects the baby to the increased risks of prematurity. Other hazards include the possible increased risk of hyperbilirubinemia, or the increase of blood break-down products in these babies, and possibly a higher rate of cesarean section in this group. The advantages might include a psychologically positive attitude in a mother who had a firm date as to when her baby would be born; a labor continuously supervised from start to finish, rather than perhaps one-third or one-half of the labor occurring without any supervision; the ability to intervene in an emergency at any point, since the patient is indeed being supervised; and the handling of an emergency by the full daytime staff pattern of the hospital rather than the sometimes sparse and slower reaction capability of night and weekend hospital personnel.

In summary, physiologic findings which may cause some concern are not always translatable into the outcome of pregnancy. The risk/benefit ratio for elective induction of labor is as yet unanswered.

Concern has been expressed over reports of increasing cesarean section rates in the United States in recent years. Some have linked the increasing frequency of cesarean section to the use of monitoring devices in labor. However, the published experience of several institutions does not bear this out. A review by J. T. Parer in Seminars in Perinatology in April, 1978, pointed out that some hospitals reported that their cesarean section rates actually decreased with the introduction of universal monitoring. Shenker reviewed the New York experience and reported that cesarean sections for fetal distress did not increase, although the primary cesarean section rate had increased over the past ten years apparently unrelated to fetal monitoring. A report from Evanston Hospital showed an increase in cesarean section rates from 1968 to 1975, but most of this change was due to changing concepts of the management of breech presentations,the management of prolonged labor, and the increasingly common belief that a cesarean section is less traumatic to the mother and particularly to the fetus than a difficult midforceps delivery. A recent review of the experience of Wesson Women's Hospital in Springfield, Massachusetts published in the February Journal of Obstetrics and Gynecology reported an increase over the last 38 years in the cesarean section rate and a rather marked increase since 1972. However, they too concluded that the increase was due primarily to an increasing number of cesarean sections for cephalopelvic disproportion (a belief that the baby was too large to pass through the pelvis without damage), labor abnormalities, and breech presentation. Less than one-fifth the increase was due to an increasing frequency of diagnosis of fetal distress.

In summary, all of the recent studies seem to indicate an increased incidence of cesarean section, but only a small portion of this related to the use of monitoring and the identification of fetal distress. It has been my impression that most of the changes from outside the profession related to the increasing cesarean section rate have come from those individuals who oppose the use of monitoring and have seized upon the increasing cesarean section rate as a means of discrediting monitoring. This is, in my opinion, a gross distortion of fact. The fact is, that knowledge which has become available in recent years has led us to question some of the practice patterns of the past which produced infant damage from long, difficult labors, traumatic forceps deliveries, and difficult manipulation of the fetus at delivery. This knowledge and the resulting changes in practice patterns have allowed us to continue to improve the perinatal outcome in the

United States today. The increasing incidence of cesarean section thus represents a step forward from the days when the excellence of an obstetrical service was judged by how low the cesarean section rate could be maintained. Some small part of the current increase is certainly due to the use of monitoring, and this is as it should be. Monitoring allows us for the first time to recognize early signs of fetal distress before the baby is permanently damaged. If vaginal delivery is not feasible, the only other form of intervention is cesarean section. Not to act in this way in a situation in which the fetus is in jeopardy, would be the utmost in therapeutic nihilism.

I would like to express my appreciation to the committee for the opportunity to speak here today. Responsible answers must be presented when questions are raised. When no generally accepted consensus can be determined, then work must be done to seek the answers to the critical questions. In the final analysis, we all desire the common goal of an improved outcome of pregnancy for the women of the United States.

Dr. Smith
Page 1

My name is Leonard Smith. I am a practicing obstetrician in Hyannis, Massachusetts and have been practicing there for 14 years. I am the Chairman of the Department of Obstetrics and Gynecology at the Cape Cod Hospital and the Chairman Elect of the Massachusetts Section of The American College of Obstetricians and Gynecologists.

The practice of obstetrics has changed dramatically since my beginning 14 years ago. Initially, we as obstetricians were concerned with having a live mother and a live baby as a successful outcome of pregnancy care. With the dramatic improvement of maternal and fetal mortality, we are becoming considerably more concerned about the quality of life for which we are responsible. We as obstetricians are in the labor and delivery suite responsible for two lives with respect to life expectancies of 70 years for the infant and 30-55 years for the mother. And with the excellent and dramatic improvement of the mortality rates as described by Dr. Ryan, we now have the more extensive concern to ensure that mother and child are not only alive but healthy.

Consequently, many things are changing in obstetrical care in this country. As you have heard from Dr. Paul, we have fetal monitors. Fourteen years ago I had very little idea of the status of the infant in labor except for the transitory every fifteen minute auscultation of the baby's heartbeat with a stethoscope. With the aid of a monitor, I can now know what the every minute status of this infant is. I can know whether the stress of labor is or is not affecting the child.

I have found very little patient objection to the use of a monitor. To the contrary, it has proven in most instances to be reassuring, not only to the obstetrician, but also to the patient herself for she can see visually that the baby's heartrate is doing well. The most frequent question of both expectant mother and father is "Is everything going okay?" Now they can see for themselves.

In addition the monitor can aid us in determining the rate and efficacy of patients' labor contractions and it is one of our tools in determining whether oxytocin augmentation is necessary to increase the effectiveness of uterine contractions. There is a place for oxytocin in an instance such as this when the uterus is not contracting properly. There is in addition use for oxytocin in induction for many medical reasons such as diabetes, Rh problems, hypertension, premature ruptured membrane, and numerous other situations in which the infant would be better outside the uterus. There are other indications for oxytocin induction which are not related to a specific disease entity. A good example of that would be the patient who lives in Provincetown, and is 55 minutes from the Cape Cod Hospital, and delivered her last baby after an hour of labor.

A striking change in the delivery of care in obstetrics has been the change in approach to cesarean section. Fourteen years ago most obstetrical services, including my own, took pride in keeping their cesarean section rate per 100 deliveries as low as possible. Again, our aim was primarily a live baby. This concept necessitated traumatic, difficult forceps deliveries, prolonged arduous labors, and birth injuries both to mother and child. A noted professor of obstetrics once said that he could not remember a cesarean section he wished he had not done, but he could remember many vaginal deliveries he wished he had done by cesarean section. And in effect this is what is now occurring. Gone are the traumatic forceps deliveries. Gone are most of the anxieties of delivering breech babies and watching them have great difficulty breathing or with severe injury. Gone are the 24 or 30-hour long labors endured by many exhausted mothers to be.

I am sure that concern exists about the cost increase of the rise in cesarean sections and I can agree with that concern, but let me mention briefly two studies as they relate to breech deliveries. First in Sweden, a retrospective study was done comparing school children who were born in breech presentation versus those born in vertex or head first presentation. The breech delivery group had essentially twice as many difficulties with reading and writing, with visual and auditory problems and with speech disorders than did the vertex delivery group. In New York City a retrospective study showed the perinatal mortality rate to be three times higher in breech delivery and the traumatic morbidity rate to be similarly three times greater. My point with these two studies is to point out that a child with physical and intellectual disabilities will equally present a cost increase in attempting to rehabilitate the child, and in the long run it may be far more cost-effective to have the rising cesarean section rates--not to mention what it could mean to the child as an individual.

In summary, like any husband and expectant father I was always extremely concerned when my wife was in labor with our children. I would be far less concerned today. The present day care of pregnant women has, in my opinion, greatly improved over even 10 years ago. I am sure that in 1988 we will look back on today and say the same thing. It is very possible that what we consider good obstetrical practices today may prove to be outdated then. Because medicine, thank God, marches on. We obstetricians are continually trying to improve, not only the mortality rate, but the quality rate by audits, by ongoing comparative studies, by long-term retrospective evaluations, by research, et cetera. Our basic concept has been and will continue to be that every child has the right to be well born.

The Alexandria Hospital
J. Edward Sweet, Jr., Administrator
4320 Seminary Road
Alexandria, Va. 22314
Telephone: 370-9000

April 26, 1978

Dr. Larry Horowitz
Staff Director
Senate Subcommittee on Health &
Scientific Research
Room 4220
Dirksen Senate Office Building
Washington, D.C. 20510

Dear Doctor Horowitz:

Per your staff's request, we are bringing to your attention an error which appeared in a recent survey, performed under the auspices of the Senate Health and Scientific Research Subcommittee. The survey determined usage of electronic monitoring during labor and its relationship to Caesarean sections performed. An unfortunate error on our part was made and reported to the surveyor.

Your results, reported nationally and featured in The Washington Star (April 17), incorrectly stated that "42.5 percent of all deliveries were by Caesarean section" at Alexandria Hospital last year. Subsequent to release of your report, a more thorough analysis determined that an inadvertent clerical error reversed the numerator with the denominator in the Caesarean rate calculation; hence, the incorrect computation. The correct Caesarean percentage for calendar year 1977 was 23.5 percent. It is requested that you make the appropriate correction to the record.

On closer examination, we question the survey's format, as it creates an opportunity for misinterpretation. Provisions were not made to group similarly sized facilities and obstetrical-gynecological departments nor equivalent services and sub-specialties to facilitate objective comparison. Likewise, the report failed to consider various origins, socio-economic status, age groupings, pregnancy risk factors within patient populations, nor was the methodology clearly defined by the surveyor. Moreover, nothing was committed to writing, thus adding potential for error or misinterpretation.

With future surveys, the subcommittee would be better informed if the following were incorporated:

1. Written survey forms should be used rather than telephone inquiries to assure consistency with terminology in requesting information.

2. Reporting periods and methodology for collecting data should be clearly defined, so as to avoid "apples to oranges" comparison.

3. Results should be grouped according to size and scope of facilities/specialties.

Unlike other facilities, the Alexandria Hospital has experienced a growth in deliveries. This increase is attributable, in part, to our hospital's multifaceted, family centered maternal child health approach, which includes extensive educational and philosophical techniques and viable supportive systems, such as neonatology, intensive care nursery and modern equipment.

Your understanding of our miscomputation and an assurance to correct the public record is appreciated. We look forward to following your committee's future activities.

Thank you.

Sincerely yours,

J. Edward Sweet, Jr.
Administrator

Copies to:
Health Scientific Research
Subcommittee Members

Year	Birth Rate	Fertility Rate	Perinatal Mort.	Neonatal Mort.	Infant Mort.	Maternal Mort.
1966	18.4/1000	91.3/1000	32.4/1000	17.2/1000	23.7/1000	29.1/100,000
1967	17.8	87.6	31.6	16.5	22.4	28.0
1968	17.5	85.7	31.4	16.1	21.8	24.5
1969	17.8	86.5	29.7	15.6	20.9	22.2
1970	18.4	87.9	28.9	15.1	20.0	21.5
1971	17.2	81.8	27.3	14.2	19.1	18.8
1972	15.6	73.4	26.0	13.6	18.5	18.8
1973	14.9	69.2	24.9	13.0	17.7	15.2
1974	14.9	68.4	23.5	12.3	16.7	14.6
1975	14.8	66.7	22.1	11.6	16.1	12.8
1976	14.8	65.8	21.2	10.9	15.2	12.3

Fertility Rate: Women of child bearing age
Birth rate: entire population
perinatal: 20 weeks of gestation-28 days old
neonatal: birth-28 days
infant: 28 days-1 yr.

Data supplied by National Center for Health Statistics

INFANT MORTALITY RATES: SELECTED COUNTRIES, FROM THE 1975 DEMOGRAPHIC YEARBOOK OF THE UNITED NATIONS

(Rates are deaths under one year of age per 1,000 live births)

Rank	Country	Rate	
1	Sweden	*8.3	
2	Finland (1974)	*10.2	
3	Norway (1974)	*10.5	
4	Netherlands	*10.6	
5	Japan (1974)	10.8	
6	Denmark (1973)	11.5	
7	Switzerland (1974)	12.5	
8	Singapore	*13.9	
9	Canada (1974)	15.0	
10	France (1973) 1/	*15.5	
11	German Democratic Republic (1974)	15.9	
12	UNITED STATES (197[illegible])	16.1	16.7 in 1977
13	Belgium (1974)	*16.2	
13	New Zealand (1973)	16.2	
15	United Kingdom (1974)	*16.3	
16	Australia (1973)	16.5	
17	Ireland (1974)	*17.1	
18	Austria	20.8	
19	Czechoslovakia	*20.9	
20	Federal Republic of Germany (1974)	*21.1	
21	Israel	22.0	
22	Italy (1974)	*22.6	
23	Bulgaria	*22.9	
24	Greece	*24.1	
25	Poland	*24.8	
26	Spain (1971) 2/	*25.4	
27	Jamaica (1974)	26.3	
28	U.S.S.R. (1974) 3/	27.7	
29	Cuba (1974)	28.9	
30	Hungary	*32.6	
31	Costa Rica (1974)	37.6	
31	Trinidad and Tobago	*37.6	
33	Romania (1974)	35.0	
34	Portugal (1974)	37.9	
35	Yugoslavia	40.5	
36	Sri Lanka (1972)	45.1	
37	Uruguay (1972)	45.4	
38	El Salvador (1974)	*58.3	
39	Chile (1971)	77.8	
40	Guatemala (1973)	81.2	

* Provisional

May 16, 1978

Dear Dr. Kennedy:

As you will recall, the Senate Human Resources Subcommittee on Health and Scientific Research held hearings on the safety of modern obstetrical practices on April 14, during which you testified on such subjects as drugs, elective induction of labor, and ultrasound.

In connection with that hearing, I have received a number of questions regarding several statements you included in your testimony and would appreciate further documentation of these statements.

On page 3 of your testimony you stated:

> "Useful drugs -- such as anesthetics to relieve pain and oxytocins to advance labor -- can, when misused or overused, result in increased risk to the patient and distress to the fetus."

On pages 12 and 13 of your statement you said:

> "Considerable experience, however, shows that obstetric analgesia and anesthesia, when judiciously employed, are usually beneficial tather than detrimental to the mother; adverse effects on the infant are not usually a serious problem." and,

> "Demerol, like other narcotic analgesics, causes mild respiratory depression in some cases. But when the drug is used judiciously the depressing effects are usually readily reversible by modern resuscitating techniques and counteracting drugs."

In other places in your testimony you indicated that the long-term effects of these drugs and other devices and practices have not been adequately examined and that epidemiological studies should be undertaken to determine the consequences. In the context of these cautionary statements, I am concerned with your use of phrases like "misused or overused" and "when judiciously employed." I would appreciate your clarifying these remarks, particularly as these drugs are used in women who are experiencing normal, healthy, uncomplicated pregnancies. I recognize that the benefits most likely outweigh the risks in high-risk pregnancies, but I am concerned that this may not be so in low-risk pregnancies.

I would appreciate your prompt attention to this inquiry, as I would like to include your response in the record on this hearing.

With best wishes,

Sincerely,

Jacob K. Javits

The Honorable Donald Kennedy
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

AUG 14 1978

Honorable Jacob K. Javits
Member, Committee on Human
  Resources
United States Senate
Washington, D.C. 20510

Dear Senator Javits:

Your May 16, 1978 letter asks for supportive documentation and clarification of the following statements in my testimony on obstetrical practices before the Senate Human Resources' Subcommittee on Health and Scientific Research on April 17, 1978:

> "Useful drugs--such as anesthetics to relieve pain and oxytocins to advance labor--can, when misused or overused, result in increased risk to the patient and distress to the fetus." (page 2)
>
> "Considerable experience, however, shows that obstetric analgesia and anesthesia, when judiciously employed, are usually beneficial rather than detrimental to the mother; adverse effects upon the infant are not usually a serious problem." (page 12)
>
> "Demerol, like other narcotic analgesics, causes mild respiratory depression in some cases. But when the drug is used judiciously, the depressing effects are usually readily reversible by modern resuscitating techniques and counteracting drugs." (page 13)

The statements on anesthetics in my testimony are meant to apply to normal, uncomplicated pregnancies as well as complicated ones. I want to caution, however, that I am referring only to immediate or relatively short-term effects. As I stated in my testimony, possible long-term effects have not as yet been examined adequately, and epidemiologic studies are needed. This is true for many drugs taken during pregnancy. Such epidemiologic studies require large numbers of patients and prolonged followup and are not feasible until drugs have been used in a large patient population. It is our intent to solicit advice from the medical profession concerning the feasibility of conducting large scale epidemiologic studies to obtain data about possible long-term effects in the offspring from drugs administered to the mother during labor and delivery.

In my statement regarding Demerol, I very deliberately used the phrase "when the drug is used judiciously." The labeling for Demerol as an obstetrical analgesic mentions that the drug may have an effect on the newborn, and that resuscitative measures may at times be necessary. It has been shown through extensive clinical experience that when the drug is properly utilized in labor the effect on the infant is usually not a serious problem, and ordinarily is readily reversible by appropriate measures.

The phrases "misused or overused" and "when judiciously employed" were not intended to imply that there is absolutely no risk involved when a drug is properly or judiciously used. As you know, no drug is totally devoid of all risk to the patient and/or to the newborn, as the case may be. Nevertheless, as I stated in my testimony, proper use of drugs during labor provides minimal risk to mother and child.

Obviously, the physician's professional judgment is a major factor in how a drug is used; whether the drug is properly used or misused is dependent upon the physician's benefit-to-risk decisions. The Agency presently is revising the oxytocic drug labeling to provide the most current information so that these decisions can be made for the maximum benefit of both mother and child. (A draft copy of the labeling is enclosed for your information).

I hope this explanation is helpful. If I can be of further assistance, please let me know.

Sincerely yours,

Donald Kennedy
Commissioner of Food and Drugs

Enclosure
Draft Labeling for
Oxytocin Injection

Senator **Kennedy**. The subcommittee stands in recess.

[Whereupon, at 1:16 p.m., the hearing was adjourned.]

○